

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL
INDUSTRY AVERAGE
WHOLESALE PRICE LITIGATION

)
) MDL No.1456
)
) Master File No. 01-CV-12257-PBS
) Subcategory No. 06-CV-11337-PBS
)

THIS DOCUMENT RELATES TO:
United States of America ex rel. Ven-A-Care
of the Florida Keys, Inc., et al. v.
Boehringer Ingelheim Corporation, et al.,
Civil Action No. 07-10248-PBS

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) Judge Patti B. Saris
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**RESPONSE TO CORRECTED BOEHRINGER INGELHEIM CORPORATION AND
BOEHRINGER INGELHEIM PHARMACEUTICAL INC.
LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT**

I. BIC, BIPI And Roxane Were Separate Legal Entities With Distinct Business Purposes

1. Boehringer Ingelheim Corporation (“BIC”) is incorporated in Nevada and has its principal place of business in Ridgefield, Connecticut. BIC serves as the parent company of Roxane, BIPI and several other U.S. subsidiaries. (United States’ First Amended Complaint ¶ 13 (“First Am. Comp.”); Tab 15, McIntyre Dep. 22-23; Tab 32, RLI-ORG00000016 (Jan. 1998 Organization Chart); Tab 33, RLI-ORG00000023 (Jan. 2000 Organization Chart))

United States’ Response: Undisputed. Further answering, BIC and its subsidiaries are part of the Boehringer Ingelheim worldwide group of companies which, during the relevant time frame, constituted the largest privately held pharmaceutical company in the world. (2/28/2009 Declaration of James J. Fauci Submitting Exhibits in Response to Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceutical Inc. Local Rule 56.1 Statement of Undisputed Material Facts In Support of Their Motion for Summary Judgment (hereinafter, “BIC/BIPI Fauci”) Exhibit 1) Roxane press releases identified the company as part of the “Boehringer Ingelheim worldwide group of companies” and described the “Boehringer Ingelheim group” as “one of the 20 leading pharmaceutical corporations in the world.” (BIC/BIPI Fauci Exhibit 2)

2. BIC is largely a holding company with very few employees. (Tab 24, Tetzner Dep. 64; Tab 15, McIntyre Dep. 22-23; Tab 2, 10/31/08 Berkle Dep. 29-30; Tab 32, RLI-ORG00000016 (Jan. 1998 Organization Chart); Tab 33, RLI-ORG00000023 (Jan. 2000 Organization Chart))

United States’ Response: Undisputed. Further answering, Roxane documents describe BIC as having “[l]imited corporate functions” and identify BIC’s subsidiary, Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”), as the “Primary Operating Company” for Boehringer Ingelheim’s various United States businesses. (BIC/BIPI Fauci Exhibit 3, at RLI-AWP-00107354)

Consistent with BIPI’s status as the primary operating company, “[h]idden’ corporate functions” for the Boehringer Ingelheim group of companies such as human resources, legal, information

technology and finance and administration were located within BIPI. (*Id.*)

In 2003, Boehringer Ingelheim considered various options for restructuring its businesses in the United States. According to a September 2003 presentation regarding the “U.S. Business of Boehringer Ingelheim,” there was no requirement to maintain BIC as a holding company and “there [wa]s no significant business advantage to keeping BIC, as the ‘corporate veil’ would likely be pierced in case of any litigation.” (*Id.*, at RLI-AWP-00107358; *see also* BIC/BIPI Fauci Exhibit 4, at RLI-AWP-00114116)

3. BIC has never owned, manufactured, marketed, or sold any pharmaceutical products and has no active business of its own. (Tab 15, McIntyre Dep. 22-23; Tab 14, 5/31/07 Marsh Dep. 21)

United States’ Response: Undisputed. (*See supra* United States’ Response to Paragraph 2)

4. BIC has its own Board of Directors and officers. (Tab 2, 10/31/08 Berkle Dep. 325, 358-362)

United States’ Response: The United States does not dispute that BIC had a Board of Directors. Further answering, from 1996 through at least 2006, the composition of BIC and BIPI’s respective Boards of Directors was identical, except that Walter Poerschmann served only on BIC’s board from 2004 through 2006. (BIC/BIPI Fauci Exhibit 5 (Roxane’s Response to Interrogatory 1, at 3-6); *see also* BIC/BIPI Fauci Exhibit 6 (10/19/2004 Tetzner Dep.), at 61:15 - 61:25) In addition, the BIC and BIPI Boards of Directors held joint board meetings from 1996 through at least 2003. (*See, e.g.*, BIC/BIPI Fauci Exhibit 7; BIC/BIPI Fauci Exhibit 8; BIC/BIPI Fauci Exhibit 9; BIC/BIPI Fauci Exhibit 64) Roxane business regularly was discussed at BIC/BIPI Board meetings, and important decisions about Roxane’s business were at times made at such meetings. (*See, e.g.*, BIC/BIPI Fauci Exhibit 8, at BICJURIS at 0176-77; BIC/BIPI Fauci

Exhibit 9, at BICJURIS0193-94; *see also infra* United States' Response to Paragraph 27)

5. Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a wholly-owned subsidiary of BIC, and is also located in Ridgefield, Connecticut. It was incorporated under the laws of Delaware. (Tab 29, 5/11/07 Waterer Dep. 523; Tab 14, 5/31/07 Marsh Dep. at 21; First Am. Comp. ¶ 14) BIPI is in the business of marketing and selling brand-name, patent-protected pharmaceutical products. (Tab 2, 10/31/08 Berkle Dep. 29; Tab 15, McIntyre Dep. 21)

United States' Response: Undisputed. Further answering, Boehringer Ingelheim employees at times referred to BIC and/or BIPI as "Connecticut" or the "Connecticut office." (*See, e.g.*, BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 36:5 - 36:22; BIC/BIPI Fauci Exhibit 11 (10/24/2001 Waterer Dep.), at 168:24 - 170:5; BIC/BIPI Fauci Exhibit 12 (12/4/2008 Sykora Dep.), at 95:8 - 96:21)

6. BIPI has its own FDA labeler code that is assigned to the BIPI-labeled products it markets and sells. BIPI's labeler code is 00597. (Tab 35, Food & Drug Administration National Drug Code Directory, *available at* <http://www.accessdata.fda.gov/scripts/cder/ndc/queryndcfn.cfm>)

United States' Response: Undisputed.

7. BIPI has its own marketing department and budget. (Tab 2, 10/31/08 Berkle Dep. 323-24)

United States' Response: The United States does not dispute that BIPI had employees whose titles indicated they had marketing responsibilities, or that BIPI had a budget related to marketing activities. The United States disputes this paragraph to the extent it suggests that BIPI's marketing personnel did not participate in marketing decisions for Roxane's products, including for the Subject Drugs. Employees in BIPI's marketing department regularly participated in such decisions, including decisions to set inflated AWP's. Whether BIPI had "its own" marketing department and/or budget is immaterial to whether BIPI was involved in the conduct for which the United States is seeking damages.

Further answering, in or around 1994, Sheldon Berkle became an Executive Vice President of Marketing at BIPI and assumed “the newly created position ‘Head of Business Unit Ethical Pharmaceuticals USA.’” (BIC/BIPI Fauci Exhibit 13; BIC/BIPI Fauci Exhibit 14)

Although Mr. Berkle served on Roxane’s Board of Directors, he never was an officer at Roxane and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 53:1 - 53:18) Through at least 2000, the Business Unit Ethical Pharmaceuticals (sometimes referred to as the “Business Unit” or the “BU”) included BIPI and Roxane’s businesses, as well as the business of a third Boehringer Ingelheim entity, Ben Venue Laboratories. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 57:14 - 58:16; BIC/BIPI Fauci Exhibit 16, at BICJURIS0236; BIC/BIPI Fauci Exhibit 17, at RLI-AWP-00162483; BIC/BIPI Fauci Exhibit 18, at RLI-AWP-00161738) From at least 1994 through 2000, senior executives at Roxane, including Edward Tupa (Vice President, Sales and Marketing) and Frederick Duy (Vice President, Business Planning and Development), reported “functionally” to Mr. Berkle in his capacity as Head of the Business Unit. (BIC/BIPI Fauci Exhibit 13, at RLI-AWP-00161743; BIC/BIPI Fauci Exhibit 19 (11/10/2005 Tupa Dep.), at 52:6 - 52:20; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 48:19 - 51:4, 53:2 - 54:16; BIC/BIPI Fauci Exhibit 11 (10/24/2001 Waterer Dep.), at 217:8 - 218:3 (noting that “Shelly Berkle, for a period of time, headed up the sales and marketing of both BIPI and Roxane”)) According to Mr. Duy, if he was going to make a “significant move with respect to a drug,” he needed to obtain Mr. Berkle’s approval. (BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 53:2 - 54:16)

An October 23, 1998, Employee Bulletin announced several organizational changes designed to increase management of “the Business Unit as a unified and focused organization.”

(BIC/BIPI Fauci Exhibit 18) Although “separate legal entities” would be preserved for BIPI, Roxane and Ben Venue Labs, the 1998 changes were designed to achieve “much greater synergy across the entire Business Unit.” The changes included, among other things, “increasing the degree of collaboration between the marketing of [Roxane] product lines and BIPI product lines,” and creating a “unified pricing process for the Business Unit.” (*Id.*, at RLI-AWP-00616739-40)

The extent of BIPI’s participation in the marketing of Roxane’s products can be seen in the launch of Roxane’s ipratropium bromide (sometimes referred to as “IBUDV”) product in June 1996. In or around September of that year, BIPI expected to lose patent exclusivity for its Atrovent Unit Dose Vial (“UDV”) product. (BIC/BIPI Fauci Exhibit 21, at ROX-TX 01341) According to minutes from an October 5, 1995 meeting of the BIPI Board of Directors, BIPI pre-empted the possibility of generic competition “through *its* planned launch of a generic by [Roxane] prior to another generic’s entry into the market.” (BIC/BIPI Fauci Exhibit 22, at BOEH02605569 (emphasis supplied)) On October 26, 1995, David Townley (an employee at Boehringer Ingelheim’s parent company in Germany) sent an email to senior officials in the Roxane and BIPI marketing departments (including Mr. Tupa and Mr. Berkle) regarding Unit Dose Vial strategy. (BIC/BIPI Fauci Exhibit 23) Mr. Townley discussed various approaches to “defend against generic erosion of Atrovent from non-BI companies” and advised that:

This should be from a total USA perspective, *ie. BIPI and Roxane combined strategy*. For example how much Ipratropium UDV business can Roxane take from BIPI and how do we “shut out” other non-BI generics as far as possible.” What is likely to be the change in price levels? Does offering a bundle of UDV substances assist and by how much?

(*Id.*) (emphasis supplied)

On or about January 24, 1996, representatives of Roxane Laboratories (including Ed Tupa

and consultant Mark Pope) met with representatives of BIPI to discuss the approaching launch of ipratropium bromide and to develop a “rudimentary strategy to achieve success within this market.” (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 109:15 - 111:16; BIC/BIPI Fauci Exhibit 24, at RLI-AWP-00299558) Minutes from this meeting were sent to Mr. Berkle. (*Id.*) The meeting included discussion of “Medicare reimbursement” and the pricing structures for Atrovent and ipratropium bromide including, specifically, that the AWP for ipratropium bromide was to be set at 10% below Atrovent's AWP. (*Id.*, at RLI-AWP-00299559-60)

According to the meeting minutes:

It was Roxane’s understanding that BIPI will maintain their current price structure and allow business that is price sensitive to convert to the Roxane product. An agreement must be made and closure should be put on this issue as early as possible. It should be noted that the AWP for IBUDV will be 10% below Atrovent’s AWP at the time of launch, contract pricing still needs to be finalized but the estimated average selling price for 1996 is \$21.00.

(*Id.*, at RLI-AWP-00299559-60) The AWP for ipratropium bromide ultimately was set at \$44.06, which was 10% below Atrovent’s AWP. (BIC/BIPI Fauci Exhibit 21, at ROX-TX 01344) According to the April 17, 1996 ipratropium bromide marketing plan, this type of price structure was used to create an attractive spread between WAC and AWP and thereby “entice” accounts to switch from the brand name to the generic product. (*Id.*) Mr. Tupa testified that he believed Mr. Berkle was involved in the decision to approve the ipratropium bromide marketing plan. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.), at 36:15 - 37:17)

Ipratropium bromide was launched in June 1996, several months prior to the expiration of patent exclusivity for Atrovent. The decision to launch ipratropium bromide preemptively allowed customers to “enjoy substantial profits” but “cost” the innovator company (i.e., BIPI) “a

lot of money,” due to sales migrating to Roxane instead of BIPI while BIPI still enjoyed patent protection. (BIC/BIPI Fauci Exhibit 26; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 147:19 - 148:7) Mr. Berkle testified that the decision to allow Roxane to launch ipratropium bromide preemptively had no long term strategic benefits to BIPI, but that the decision was beneficial to the “Boehringer family” of companies. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 119:6 - 120:20) Mr. Berkle also testified that Roxane and BIPI worked together “to try and maintain the Ipratropium business whether it be Atrovent or otherwise within the Boehringer family of companies.” (*Id.*, at 91:16 - 92:13)

When Roxane had trouble supplying ipratropium bromide orders in late 1996, it filled such orders with Atrovent instead. (BIC/BIPI Fauci Exhibit 27) Although the average selling price for Atrovent was approximately \$35.00, Roxane obtained Atrovent and sold it to customers at the significantly reduced “generic price.” (*Id.*; BIC/BIPI Fauci Exhibit 26) Roxane expected that customers “who get their hands on Atrovent at the distressed price” would use it for brand as well as generic sales, and that customers would use the brand as a “hook” to increase sales. (BIC/BIPI Fauci Exhibit 27, at RLI-AWP-00431168-69)

8. BIPI has its own sales force that promotes BIPI products. (*Id.*)

United States’ Response: The United States does not dispute that BIPI had sales personnel with responsibility for promoting BIPI products. The United States disputes this paragraph to the extent it suggests that Roxane and BIPI had separate sales forces, or that BIPI sales personnel did not promote Roxane’s products. Whether BIPI had “its own” sales force is immaterial to whether BIPI was involved in the conduct for which the United States is seeking damages.

Further answering, BIPI sales personnel promoted Roxane’s products, including the

Subject Drugs. For example, on or about May 17, 1996, James King sent an email to the BIPI sales force announcing that Roxane's promotion of ipratropium bromide began on June 3 of that year, and advising sales personnel that "if Roxane's ipratropium bromide is sold, or if an Atrovent solution is sold, you get credit for it." (BIC/BIPI Fauci Exhibit 28; *see also* BIC/BIPI Fauci Exhibit 29) Beginning in at least 1998, Mr. King began supervising both the BIPI and "RLI branded" sales forces (with responsibility for selling Subject Drugs Roxicodone and Oramorph SR), and running a "sales training group" at Roxane. (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 15:2 - 15:23, 25:15 - 26:8; BIC/BIPI Fauci Exhibit 18, at RLI-AWP-00161739) Mr. King testified that although he supervised Roxane sales personnel, he was employed in the BIPI sales department for his entire career and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 11:13 - 12:4, 24:14 - 24:25)

In addition, from at least 1996 through approximately 2001, "National Accounts Managers" in the Business Unit's "Trade Relations Group" promoted both the Roxane and BIPI product lines to chain drug stores, wholesalers and large national buying groups. (*See, e.g.*, BIC/BIPI Fauci Exhibit 31) The National Account Managers promoted the Roxane and BIPI product lines to wholesalers and other important customers through at least 2001. (*See, e.g.*, BIC/BIPI Fauci Exhibit 35 (1/25/2005 Gordon Dep.), at 19:14 - 21:9; BIC/BIPI Fauci Exhibit 37 (12/2/2005 Doan Dep.), at 43:19 - 44:8; BIC/BIPI Fauci Exhibit 38 (11/22/2005 Tavoraro Dep.), at 57:17 - 59:1) Specifically, in or around 1996, Mr. Tupa hired Richard Feldman as Director, Trade Relations, with responsibility for promoting both the Roxane and BIPI product lines. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.), at 137:9-138:14; BIC/BIPI Fauci Exhibit 32 (noting that Mr. Tupa is "in the process of recruiting for the position of Director, Trade and

Pharmacy Affairs which will focus greater attention on this critical aspect of both the BIPI and Roxane businesses”); BIC/BIPI Fauci Exhibit 33 (11/18/2005 Feldman Dep.), at 59:2 - 60:22) Mr. Feldman had responsibility for promoting Roxane and BIPI products until approximately 2001, when he began to promote only BIPI products. (BIC/BIPI Fauci Exhibit 34 (11/17/2004 Feldman Dep.), at 108:24 - 109:25) After 2001, it was decided that Roxane and BIPI should have their own Trade Relations groups, and the employees in the Trade Relations unit were split between Roxane and BIPI. (*See, e.g.*, BIC/BIPI Fauci Exhibit 35 (1/25/2005 Gordon Dep.), at 19:23 - 21:9)

Reporting to Mr. Feldman was Robert Sykora, who served as the director of approximately six to eight National Account Managers. (BIC/BIPI Fauci Exhibit 36 (11/2/2005 Sykora Dep.), at 25:16 - 25:23, 27:8 - 28:18) Mr Sykora testified that although he was employed and paid by BIPI, he primarily worked for Roxane. (*Id.*, at 22:20 - 23:5; BIC/BIPI Fauci Exhibit 12 (12/4/2008 Sykora Dep.), at 49:20 - 50:3)

9. BIPI has its own customers that it contracts with and invoices. (*Id.* 313-14, 322)

United States’ Response: The United States does not dispute that BIPI had customers that it contracted with and invoiced. The United States disputes this paragraph to the extent it suggests that Roxane and BIPI did not share customers or market products jointly. Whether BIPI had “its own” customers is immaterial to whether BIPI was involved in the conduct for which the United States is seeking damages.

Further answering, Roxane and BIPI jointly marketed products to customers. For example, in or around August 1996, personnel at Roxane and BIPI discussed the possibility of cooperatively marketing ipratropium bromide to Kaiser, a large group purchasing organization

(“GPO”), including by offering better prices if Kaiser committed to purchasing both Roxane and BIPI products. (BIC/BIPI Fauci Exhibit 39) Kaiser ultimately accepted a “bundled agreement” for ipratropium bromide and Atrovent. (BIC/BIPI Fauci Exhibit 40) Judy Waterer explained that “[t]his is another first for us in showing what we can accomplish when we combine the strength of Roxane with BIPI!” (*Id.*)

Another example of joint marketing is Roxane and BIPI’s joint bid to Premier (another GPO) in 1998. Premier was at that time Roxane’s “#1 customer” and the “largest group purchasing organization.” (BIC/BIPI Fauci Exhibit 41) According to a February 27, 1998 Interoffice Memorandum sent to Mr. Berkle, the “primary goal” of the bid to Premier was to maintain the “majority contract item” for BIPI, Roxane and Ben Venue Labs. (BIC/BIPI Fauci Exhibit 42) The memorandum explained that additional discounts on BIPI products “should be held back” until it was certain that Premier “welcomes the BIC companies as a Corporate Partner.” (*Id.*)

In addition, Roxane regularly entered into contracts with customers whereby, in return for the customer’s marketshare commitment on select Roxane products, the customer received a rebate on its purchase of certain BIPI products. (*See, e.g.*, BIC/BIPI Fauci Exhibit 43, at RLI-AWP-00128923-24)

10. Roxane Laboratories, Inc. (“Roxane”) was first organized in 1885 as Columbus Pharmacal, a small, regional pharmaceutical manufacturer. Columbus Pharmacal was purchased by Philips of the Netherlands, and the name was changed from Columbus Pharmacal to Philips Roxane. (Tab 36, “Roxane Laboratories Oral Solid Dosage Facility Expansion, Columbus, OH”, *available at* <http://www.pharmaceutical-technology.com/projects/roxane/>) It was not until 1978 that Roxane became part of the Boehringer Ingelheim family. (Tab 37, “Boehringer Ingelheim in the United States is available at <http://www.us.boehringer-ingelheim.com/about-us/companyhistory>. html.; Tab 19, 10/11/05 Powers Dep. 198)

United States' Response: Undisputed.

11. Roxane was a Delaware corporation during the relevant timeframe, and is headquartered in Columbus, Ohio. (Tab 38, RLI-AWP-00000001-00000069 (1996-2004 Roxane Laboratories, Inc. Corporate Data Sheets) (Roxane Corporate Data))

United States' Response: Undisputed.

12. In April 2005, Roxane Laboratories, Inc. changed its name to Boehringer Ingelheim Roxane, Inc. ("BIRI"). (Roxane's Answer to United States' 1st Am. Compl. at 1, n.1; Tab 39, RLI-TX 7922-7923 (Roxane Reorganization Employee Announcement); Tab 40, RLI-AWP-00104259-62 (9/15/04 Reorg Letter) BIRI remains a Delaware corporation. BIRI continues to manufacture pharmaceutical products. (*Id.*) At the same time, a new entity, Roxane Laboratories, Inc., a Nevada corporation, was incorporated. (*Id.*) As of that time, the new Nevada corporation ("RLI Nevada") assumed responsibilities for sales and marketing of pharmaceutical products sold under the Roxane tradename. (*Id.*)

United States' Response: Undisputed. Further answering, the April 2005 reorganization was undertaken, at least in part, due to a recognition that Boehringer Ingelheim "operate[d] in the U.S. with a variety of legal entities that do not necessarily reflect the nature of [its] businesses," resulting "in two sets of reporting: one in terms of legal entities and another in terms of businesses." (BIC/BIPI Fauci Exhibit 44, at BICJURIS 1066). Prior to 2005, Roxane had separate reporting structures for its manufacturing business and for its sales and marketing business. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 29:14 - 30:12) There was a concern at Boehringer Ingelheim that "[t]his system often [did] not convey clearly the performance of our businesses, and le[d] to complexities in interpreting how each business is faring." (BIC/BIPI Fauci Exhibit 44) An October 13, 2004, Employee Bulletin announcing the April 2005 reorganization explained that due to organizational changes made in or around 2000, "the employee and financial reporting structures were crossing the businesses" at Roxane, BIPI and Ben Venue Labs, requiring Boehringer Ingelheim to spend a significant amount of time

trying to accurately report on the performance of each business. (BIC/BIPI Fauci Exhibit 46) The Bulletin also explained that the 2005 Reorganization would help to “better align employees with the businesses they support and the management group they report to” and to place “employees within the same legal entity they report to.” (*Id.*) Hermann Tetzner (BIC Chief Financial Officer) also testified that the reorganization was also intended to reduce potential legal liability. (Fauci Exhibit 6 (Tetzner Dep.), at 30:1 - 33:5)

Multiple Roxane employees testified that prior to 2005, Roxane and BIPI operated as intermingled companies. (*See, e.g.*, BIC/BIPI Fauci Exhibit 11 (10/24/2001 Waterer Dep.), at 13:12 - 14:1 (noting that Boehringer Ingelheim was “kind of an intermingled company”); BIC/BIPI Fauci Exhibit 47 (2/4/2003 Powers Dep.), at 40:23 - 42:1; BIC/BIPI Fauci Exhibit 48 (email from BIPI employee regarding Roxane and BIPI’s pricing process and asking “Now that we are one Corporation, should these processes be combined . . .”)) Moreover, Boehringer Ingelheim employees observed that Roxane and BIPI appeared to be one company to customers. For example, in April 1997, Jim King drafted a memorandum regarding Roxane’s pricing procedures. (BIC/BIPI Fauci Exhibit 49) In a section entitled “Recommendations,” Mr. King noted that Roxane and BIPI “do not appear too separate to people outside our Corporation,” and advised that it was important to convene a pricing committee regularly “to ensure that pricing issues are squared away at both companies.” (*Id.*, at BOEH04353265)

13. At all times relevant to this litigation, Roxane was a wholly-owned subsidiary of BIC. (Tab 29, 5/11/07 Waterer Dep. 523)

United States’ Response: Undisputed.

14. Roxane had its own employees, whom it retained the ability to hire and fire and to whom it offered its benefits plans that were different than those of its affiliates. (Tab 41,RLI-TX

17676-78 (Roxane Reorganization Human Resources Presentation))

United States' Response: The United States does not dispute that Roxane had employees over whom it retained the ability to hire and fire. However, the United States disputes that all or even most personnel who marketed and/or sold Roxane's products were Roxane employees. As noted *supra* in the United States' responses to Paragraphs 7 and 8, various BIPI personnel were involved in the marketing and/or promotion of Roxane's products, including the Subject Drugs. In fact, the two senior managers in charge of Roxane's marketing in the 1998 - 2001 time frame were Mr. Berkle and Tom Russillo, neither of whom was employed by Roxane. (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 205:19 - 207:2) Mr. Berkle was employed by BIPI, but supervised Roxane's branded generic business. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 53:1 - 53:18, 59:17 - 60:11, 262:19 - 264:12, 337:8 - 339:16, 341:17 - 342:4) Mr. Russillo was employed as the Chief Operating Officer of Ben Venue Laboratories, but was in charge of marketing for Roxane's "multi-source products." (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 22:17 - 25:3, 29:8 - 30:10)

In addition, a Roxane organizational chart from 1999 (BIC/BIPI Fauci Exhibit 50) identifies several BIPI employees as having responsibility for Roxane's drugs, including, among others, James King, Gregg Ciarelli, and Mike Leonetti.

- Mr. King testified that although he had supervised Roxane sales personnel, he was employed by BIPI for his entire career and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 11:13 - 12:4, 15:2 - 15:23, 25:15 - 26:8)
- Mr. Ciarelli testified that although he was employed and paid by BIPI for his entire tenure with Boehringer Ingelheim, (BIC/BIPI Fauci Exhibit 51 (6/26/2002 Ciarelli Dep.), at 9:17 - 10:11, 50:6 - 50:13), his job responsibilities as marketing controller encompassed the entire "Business Unit" including BIPI and Roxane.

(*Id.*, at 13:14 - 14:7) Mr Ciarelli testified that he likely appeared on a Roxane organizational chart because he “had people on the Roxane payroll that reported to [him].” (*Id.*, at 50:14 - 50:18)

Mr. Ciarelli also testified that from 1997 through 2000, he had “ongoing responsibility” for reporting prices to First Data Bank for Roxane’s branded products. (BIC/BIPI Fauci Exhibit 52 (7/25/2007 Ciarelli Dep.), at 22:10 - 24:10, 28:17 - 29:4, 49:17 - 49:21) In addition, Mr. Berkle testified that Mr. Ciarelli was responsible for ensuring that Roxane and BIPI complied with applicable laws regarding the reporting of drug prices. (BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 166:23 - 168:11)

- Mr. Leonetti worked for BIPI (BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 219:19 - 220:7; BIC/BIPI Fauci Exhibit 54 (4/3/2003 Rowenhorst Dep.), at 125:15 - 126:6), but supervised the Trade Relations Group and the “Reimbursement Manager,” each of which had responsibilities for Roxane products. (BIC/BIPI Fauci Exhibit 36 (11/2/2005 Sykora Dep.), at 26:8 - 28:11; BIC/BIPI Fauci Exhibit 54 (4/3/2003 Rowenhorst Dep.), at 181:17 - 183:7)

Effective January 2002, senior employees responsible for marketing Roxane’s multi-source products, including Judy Waterer and Leslie Paoletti, were transferred to Ben Venue

Laboratories. (BIC/BIPI Fauci Exhibit 55) From this time forward, Ms. Waterer and Ms.

Paoletti continued to have responsibility for marketing Roxane’s products even though they were employed and paid by Ben Venue Labs. (BIC/BIPI Fauci Exhibit 56 (11/9/2004 Paoletti Dep.),

at 9:25 - 10:23, 17:1 - 17:6; BIC/BIPI Fauci Exhibit 57 (7/26/2007 Paoletti Dep.), at 9:16 - 10:9;

BIC/BIPI Fauci Exhibit 58 (11/28/2005 Waterer Dep.), at 28:14 - 29:2)

15. Roxane has its own separate line of Roxane-labeled products that it marketed under its own name and labeler code. Currently, the Roxane product line consists of roughly 400-500 NDCs. (Tab 6, 5/30/07 DeCapua Dep. 167; Tab 13, 6/27/02 Marsh Dep. 117; Tab 2, 10/31/08 Berkle Dep. 320-21)

United States’ Response: Undisputed, except that BIPI at times was identified in the launch of Roxane products, including Roxicodone. For example, product announcements for Roxane’s 15 mg and 30 mg Roxicodone tablets identified the product as “From Boehringer Ingelheim/Roxane

Laboratories, Inc.” (BIC/BIPI Fauci Exhibit 59) Likewise, a promotion for Roxane’s Cafcit product (not a Subject Drug) stated that “Roxane Laboratories, Inc., in conjunction with Boehringer Ingelheim Pharmaceuticals, Inc. is pleased to announce the availability of Cafcit.” (BIC/BIPI Fauci Exhibit 106)

16. Roxane has always been primarily focused on marketing multi-source products. Until 2001, Roxane also marketed a small line of brand and branded generic products. (Tab 2, 10/31/08 Berkle Dep. 30-31; Tab 14, 5/31/07 Marsh Dep. 28-29; Tab 6, 5/30/07 DeCapua Dep. 15-16; *infra* ¶ 81)

United States’ Response: Disputed. According to a Roxane “Position Paper” from 1999, Roxane’s “largest seller” at that time was Viramune®, an HIV/AIDS drug assigned to Roxane by BIPI, which accounted for \$106 million of Roxane’s expected \$412 million in third-party net sales for 1999. (BIC/BIPI Fauci Exhibit 60, at BOEH02601796) The Position Paper described Roxane’s “branded generics” in the pain/palliative care area as “important contributors to its sales and profits.” (*Id.*) The Position Paper specifically noted that Oramorph SR, Roxicodone and Roxanol (all branded generic products and all Subject Drugs) collectively produced sales of \$40 million in 1999. (*Id.*)

17. Roxane promotes its products primarily based on price and service to wholesalers and pharmacies. (Tab 29, 5/9/07 Waterer Dep. 102-103; Tab 29, 5/11/07 Waterer Dep. 538-540) Roxane had its own customers with whom it negotiated and entered into contracts. (Tab 29, 5/11/07 Waterer Dep. 547-51, 558-59)

United States’ Response: The United States disputes that Roxane “promotes its product primarily based on price and service to wholesalers and pharmacies.” The United States refers to its Local Rule 56.1 Statement of Undisputed Material Facts As to The Roxane Defendants (M.D.# 6293, S.D.# 299), which demonstrates that Roxane knowingly set inflated AWP’s for its products and promoted increased reimbursement as a reason for customers to purchase its

products.

The United States does not dispute that Roxane had customers that it contracted with and invoiced. The United States disputes this paragraph to the extent it suggests that Roxane and BIPI did not share customers or market products jointly. Whether Roxane had “its own” customers is immaterial to whether Roxane was involved in the conduct for which the United States is seeking damages. Further answering, *see supra* United States’ Response to Paragraph 9.

18. Roxane has its own FDA labeler code, which is 00054. (Tab 18, 7/26/07 Paoletti Dep. 200)

United States’ Response: Undisputed. *See supra* United States’ Response to Paragraph 15.

19. Sales and marketing practices for brand and generic products are very different based on the nature of each market. (Tab 2, 10/31/08 Berkle Dep. 321; Tab 29, 5/9/07 Waterer Dep. 199-200; Tab 26, 10/24/01 Waterer Dep. 142-143)

United States’ Response: The phrase “very different” is ambiguous as used in this paragraph. The United States does not dispute that branded and multi-source products may be marketed according to different marketing strategies. The paragraph is otherwise disputed, and is not supported by the cited authority.

20. Brand drugs are marketed mainly to physicians, based upon their clinical benefits. (Tab 26, 10/24/01 Waterer Dep. 142; Tab 29, 5/9/07 Waterer Dep. 199-200) This is because brand drugs are patent protected, so as long as a prescription is written for that drug, it will be dispensed. (Tab 26, 10/24/01 Waterer Dep. 142-143) Multi-source generic drugs are marketed mainly to wholesalers and retail pharmacies based on service and price. (Tab 2, 10/31/08 Berkle Dep. 322; Tab 29, 5/9/07 Waterer Dep. 199-200, *supra* ¶ 17)

United States’ Response: Disputed. Roxane has failed to offer evidence to support a finding that brand drugs “are marketed mainly to physicians, based upon their clinical benefits” or that “multi-source generic drugs are marketed mainly to wholesalers and retail pharmacies based on service and price.” The United States refers to its Local Rule 56.1 Statement of Undisputed

Material Facts As to The Roxane Defendants (M.D.# 6293, S.D.# 299), which demonstrates that Roxane knowingly set inflated AWP's for its products and promoted increased reimbursement as a reason for customers to purchase its products. Further answering, Roxane marketed several multi-source products as "branded generic" products, meaning that the product was assigned a brand name and was marketed according to a branded marketing strategy. (*See, e.g.*, BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 31:8 - 31:22; BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 30:14 - 33:6)

II. Roxane Respected All Corporate Formalities And Maintained Independent Financial Records And Sufficient Capitalization.

(a) Roxane Had a Fully-Functioning Board of Directors.

21. Roxane had its own Board of Directors. From 1996 until 2005, Roxane's Board ranged in size from three to five directors, and included the following individuals: Werner Gerstenberg, Gerald Wojta, Phillip Franks, Walter Poerschman, Sheldon Berkle, Martin Carroll, and Robert Fromuth. (Tab 38, RLI-AWP-00000001-00000069 (Roxane Laboratories, Inc. Corporate Data Sheets) (Roxane Corporate Data))

United States' Response: The United States does not dispute that Roxane had a Board of Directors. The United States disputes that this board was "fully-functioning." Mr. Berkle, the only member of the Roxane Board of Directors who has been deposed, testified that the Roxane Board of Directors "was not an active board" and that "there were very, very infrequent meetings and it was more to form than anything else. It wasn't operational in other words." (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 54:9 - 54:19) Further answering, the Roxane Board of Directors met rarely if ever. (*Id.*)

22. In accordance with its bylaws and Delaware law, Roxane's Board acted through unanimous written consent, in lieu of meetings, to choose officers, directors, a chairman of the board, and to transact other company business. Roxane maintained written records of the Board's bylaws and unanimous consents. (Tab 42, BOEH04600117-21, BOEH04600151-54,

BOEH04600159-67, BOEH04600197-09, BOEH04600226-47, BOEH04600248-52; BOEH04600254-63, BOEH04600267, BOEH04600292-94, BOEH04600302-06, BOEH04600326-28, BOEH04600330-39, BOEH04600363-77, BOEH04600382-85, BOEH04600392-97, BOEH04600413-15, BOEH04600430-35, BOEH04600465-77, BOEH04600504-07, BOEH04600521-29, BOEH04600533-36, BOEH04600538-44, BOEH04600609-14 (Select Roxane Board of Directors Unanimous Written Consents 1996-2005) (Roxane Unanimous Consents))

United States' Response: The United States does not dispute that Roxane's Board of Directors at times chose officers and directors and took other actions through "unanimous written consent." The United States disputes that this is material to whether or not Roxane operated as an independent company, however. First, Mr. Berkle testified that the Roxane Board was not "active" and "was more to form than anything else." (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 54:9 - 54:19) Second, Roxane expert witness, Professor Macey, testified that at a corporation of Roxane's size, "corporate formalities" such as "board processes" and "board action" are almost always followed. (BIC/BIPI Fauci Exhibit 61 (5/20/2009 Macey Dep.), at 292:11 - 294:22) Third, Roxane has not offered any evidence to establish who created the unanimous written consents, nor whether or not they were prepared by counsel. Finally, when the Roxane Board of Directors acted through unanimous written consents, it was at times merely to confirm or formally authorize decisions that had already been made by BIC and/or BIPI. (*See infra* United States' Response to Paragraph 27)

Further answering, on several occasions, the Roxane Board of Directors simply authorized employees of Roxane's affiliate companies, including BIPI, to perform various functions with regard to Roxane's business. For example, in or around February 18, 1999, Roxane's Board of Directors acted through unanimous written consent to authorize "Gregg Ciarelli, as an employee of [BIPI] and in support of the U.S. Business Unit Ethical

Pharmaceuticals,” to execute and file contracts with vendors having a value less than \$250,000. (BIC/BIPI Fauci Exhibit 62) The Roxane Board of Directors granted similar authority to Mike Leonetti, also “as an employee of [BIPI].” (BIC/BIPI Fauci Exhibit 63)

23. Roxane’s Board approved its bylaws. (Tab 42, BOEH04600226-47 (Roxane Unanimous Consents))

United States’ Response: Undisputed, except that the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States’ Response to Paragraph 22)

24. Roxane’s Board approved financial reports and budgets. (Tab 42, BOEH04600159-67, BOEH04600197-06, BOEH04600254-63, BOEH04600302-06, BOEH04600330-39, BOEH04600363-68, BOEH04600392-97, BOEH04600430-35, BOEH04600465-77, BOEH04600609-14 (Roxane Unanimous Consents))

United States’ Response: The United States does not dispute that at times the Roxane Board approved financial reports and budgets through “unanimous written consent.” Further answering, the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States’ Response to Paragraph 22)

25. Roxane’s Board approved dividend payments to its parent company, BIC. (Tab 42, BOEH04600117-21, BOEH04600292-94, BOEH04600326-28, BOEH04600413-15 (Roxane Unanimous Consents))

United States’ Response: Undisputed, except that the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States’ Response to Paragraph 22)

26. Roxane’s Board approved decisions to file law suits. (Tab 42, BOEH04600151-54 (Roxane Unanimous Consents))

United States’ Response: The United States does not dispute that the Roxane Board approved

the decision to file the lawsuit specified in the documents referenced at Tab 42. Further answering, the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22)

27. Roxane's Board approved decisions to enter co-promotion agreements, and to acquire and divest drugs. (Tab 42, BOEH04600248-52, BOEH04600369-74, BOEH04600375-77 (Roxane Unanimous Consents))

United States' Response: Undisputed, except that the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22) Further answering, the Roxane Board of Directors' unanimous written consent authorizing the divestiture of the pain/palliative care products was dated September 28, 2001. Tab 42, at BOEH04600369 - BOEH04600371. The decision that Roxane would divest the pain/palliative care products was actually made in May 2000, at a joint meeting of the Boards of Directors of BIC and BIPI. (BIC/BIPI Fauci Exhibit 8, at BICJURIS0179-80) At another joint meeting of the BIC/BIPI Boards of Directors on June 21, 2001, Mr. Berkle reported that efforts were underway to out-license Roxane's pain and addiction products, and that offers had been received in excess of \$200 million. (BIC/BIPI Fauci Exhibit 64, at BICJURIS0122)

28. In 2005, Roxane's Board approved of the decision to restructure the company into two separate corporations, one for sales and marketing, and one for manufacturing. (Tab 42, BOEH04600504-07, BOEH04600521-29, BOEH04600533-36, BOEH04600538-44 (Roxane Unanimous Consents))

United States' Response: Undisputed, except that the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22)

29. Roxane's Board appointed officers. (Tab 42, BOEH04600159-67 (1996); BOEH04600197-06 (1997), BOEH04600207-09 (1997); BOEH04600254-63 (1998); BOEH04600267 (1998); BOEH04600302-06 (1999); BOEH04600330-33 (2000); BOEH04600363-68 (2001); BOEH04600392-97 (2002); BOEH04600382-85 (2002); BOEH04600430-35 (2003); BOEH04600465-77 (2004); BOEH04600609-14 (2005) (Roxane Unanimous Consents))

United States' Response: Undisputed, except that the United States disputes this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22)

30. Gerald Wojta was President and COO of Roxane until 1997. Following Wojta's departure, Werner Gerstenberg served as President and COO of Roxane from 1997 until 2002. Roxane's Board then appointed Robert Fromuth as President and COO, who held that position from 2002 until the 2005 split of Roxane. (Tab 38, RLI-AWP-00000058-67, RLI-AWP-00000016-58, RLI-AWP-00000001-16 (Roxane Corporate Data); Tab 42, BOEH04600207-09, BOEH04600382-85 (Roxane Unanimous Consents))

United States' Response: Undisputed. Further answering, Mr. Gerstenberg also served as the President and Chief Executive Officer of BIC during the relevant timeframe. (*See, e.g.*, BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 42:2 - 42:12; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 47:7 - 48:11, 219:20 - 220:10; BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 17:7 - 18:14; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 55:22 - 57:16) Mr. Fromuth replaced Mr. Gerstenberg as President and Chief Operating Officer of Roxane in April 2002, due to Mr. Gerstenberg's "multiple executive responsibilities" at Boehringer Ingelheim and the fact that it was deemed "in the best interests of [Roxane] to have a Chief Operating Officer on site." (Tab 42, at BOEH04600382-85)

Mr. Gerstenberg's offices were at BIC and BIPI's corporate headquarters in Connecticut, and Boehringer Ingelheim and Roxane employees regarded Mr. Gerstenberg as the President of BIC and reported to him in that capacity. (*See, e.g.*, BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 42:2 - 42:12; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 47:7 -

48:11, 219:20 - 220:10; BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 17:7 - 18:14; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 55:22 - 57:16) For example, Mr. Russillo (who supervised Roxane's multi-source marketing) testified that he reported to Mr. Gerstenberg "in his role as president and CEO of BIC." (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 29:8 - 30:10, 204:1 - 204:7, 205:19 - 207:2) The evidence supports the conclusion that Mr. Russillo reported to Mr. Gerstenberg as CEO of BIC for several reasons. First, Mr. Russillo testified that he reported to Mr. Gerstenberg both when Mr. Russillo was acting as the Chief Operating Officer of Ben Venue Labs, and when Mr. Russillo was supervising Roxane's multi-source marketing. (*Id.*) Mr. Russillo did so even though there is no evidence that Mr. Gerstenberg was ever an officer of Ben Venue Labs. Second, Mr. Russillo continued to report to Mr. Gerstenberg through 2003, *after* Mr. Gerstenberg had been replaced as President of Roxane but when Mr. Gerstenberg was still serving as President of BIC. (*Id.*) Third, Mr. Russillo testified that he reported to Martin Carroll as President of BIC, after Mr. Carroll replaced Mr. Gerstenberg in that role, even though Mr. Carroll was not an officer at Roxane. (*Id.*; *see also* BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 31:11 - 32:10.

(b) Roxane maintained separate financial records.

31. Roxane's finances were accounted for separately and independently from its parent and affiliates, and Roxane kept its own separate financial records and statements. (Tab 15, McIntyre Dep. 202; Tab 43, BOEH04600203-05 (1996 Commentary); Tab 44, BOEH02541150-69 at 54, 60 (Commentary 1997 Actual); Tab 45, BOEH02541103-22 at 06, 12 (Commentary 1998 Year End Actual); Tab 46, BOEH02584571-97 at 76, 94 (Commentary 1999 Budget 1999 Actual); Tab 47, BOEH02687778-03 at 81, 02 (Commentary 2000 Target 2000 Actual); Tab 48, BOEH02675446-72 at 49, 71 (Commentary To The Financial Statements For Year End 12/31/01); Tab 49, BOEH00147729-58 at 33, 57 (2002 Year-End Financial Commentary); Tab 50, BOEH02675333-62 at 37, 53 (Roxane Labs, Inc. Year End 2003 & Commentary); Tab 51, BOEH04295701-32 at 25, 29 (Roxane Labs, Inc. Year End 2004 & Commentary); Tab 52, BOEH02522567-99 at 91, 95 (Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc. 2005 Year End Commentary))

United States' Response: The United States does not dispute that Boehringer Ingelheim kept separate financial records for Roxane, including Profit and Loss Statements and year-end Balance Sheets. Further answering, beginning in 2001, accounting services for Roxane were performed, at least in part, by BIPI personnel. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 33:17 - 34:15)

32. During the relevant time period, a separate entity within the BIC corporate group, BI Services Center, Inc. ("BISC") provided transactional financial services for BIC's subsidiaries, such as accounts payable, accounts receivable, payroll, and customer service. (Tab 15, McIntyre Dep. 37-38, 41)

United States' Response: Undisputed. Further answering, other corporate functions such as finance and administration, legal, and information technology were performed by BIPI personnel. (BIC/BIPI Fauci Exhibit 3, at RLI-AWP-00107354; BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 37:9 - 40:22)

33. As part of the centralized financial services, BIC and its subsidiaries used a zero balance cash management system. Each legal entity had its own bank account, and at the end of each day, the money from each entity's account was swept into a combined account so it could be invested on behalf of the entities. Records were kept tracking the amount that each individual affiliate contributed or withdrew from the investment account. (*Id.* 162-163).

United States' Response: Undisputed except the phrase "had its own bank account" is ambiguous as used in this sentence, and there is no evidence to support a finding that Roxane kept its cash in a separate bank account from other Boehringer Ingelheim entities. Hermann Tetzner, who served as BIC's Chief Financial Office, testified that cash at Boehringer Ingelheim's United States companies was swept daily into "a corporate cash pool controlled by Boehringer Ingelheim in Germany." (BIC/BIPI Fauci Exhibit 6 (10/19/2004 Tetzner Dep.), at 12:16 - 12:23, 175:20 - 177:2)

34. Through the central cash management system established at the BISC, inter-company loans and short term advances to affiliates were made among BIC and its subsidiaries. The loans

and advances were accounted for and tracked by the BISC through internal accounting records. (*Id.* 126-127, 160-162).

United States' Response: The United States does not dispute that loans were made among BIC and its subsidiaries.

35. For loans and advances, the borrowing company paid interest to the lending company at a rate of LIBOR plus .25%. (*Id.* 126-127).

United States' Response: Undisputed.

(c) Roxane was sufficiently capitalized at all times.

36. Roxane's business consistently generated income and it maintained substantial retained earnings. Roxane never needed to use any funds from its capital stock or its additional paid-in capital, and the balances of each remained the same over time. Between 1995 - 2005, Roxane had an average annual net income of \$37,964,000. During that same period, it had average annual retained earnings of \$146,165,182. (Tab 42, BOEH04600164-67, BOEH04600102-06, BOEH04600258-63, BOEH04600305-06, BOEH04600335-36, BOEH04600367-68, BOEH04600396-97, BOEH04600434-35, BOEH0460046569-71, BOEH04600613-14 (Roxane Unanimous Consents))

United States' Response: The United States does not dispute that Roxane's business generated income throughout the relevant time period. The United States, however, does dispute that Roxane "maintained substantial retained earnings" throughout the time period. The United States further disputes that Roxane's "average annual net income" or its "average annual retained earnings" are relevant to an evaluation of whether or not Roxane was sufficiently capitalized at any particular point in time, or is sufficiently capitalized now. As explained in greater detail below, Roxane's retained earnings dropped dramatically in 2002, after Roxane received its first subpoena from the United States in August 2000, and following Roxane's payment of an unbudgeted \$320 million "dividend" to BIC in November 2002. (BIC/BIPI Fauci Exhibit 109, at BIC JURIS 0920 (noting that the "planned dividend" was \$75 million versus the actual dividend of \$320 million); BIC/BIPI Fauci Exhibit 66; BIC/BIPI Fauci Exhibit 67, at BOEH04600434)

From 1996 until 2002, Roxane's retained earnings grew annually, and in each year significantly exceeded Roxane's total liabilities. (BIC/BIPI Fauci Exhibit 68 (year-end 1996), at BOEH04600205; BIC/BIPI Fauci Exhibit 69 (year-end 1997), at BOEH04600262; BIC/BIPI Fauci Exhibit 70 (year-end 1998), at BOEH04600306; BIC/BIPI Fauci Exhibit 108 (year-end 1999), at BOEH04600335; BIC/BIPI Fauci Exhibit 72 (year-end 2000 and 2001), at BOEH04600396; BIC/BIPI Fauci Exhibit 67 (year-end 2002), at BOEH04600434) Roxane's retained earnings consistently exceeded total liabilities during this time period even though Roxane paid a \$41 million dividend to BIC in May 1999, and a \$50 million dividend to BIC in May 2000. (BIC/BIPI Fauci Exhibit 71; BIC/BIPI Fauci Exhibit 74) Roxane originally budgeted that its retained earnings for 2002 would be approximately \$402 million, against total liabilities of approximately \$144 million. (BIC/BIPI Fauci Exhibit 67, at BOEH04600434) However, after paying the \$320 million dividend to BIC in November 2002, Roxane's actual retained earnings for year-end 2002 were slightly more than \$46 million, against total liabilities of over \$320 million. (*Id.*) As seen in the table below, 2002 was the first year since at least 1996 when Roxane's total liabilities exceeded its retained earnings.

Year	Income	Retained Earnings	Total Liabilities
1996	\$ 39,134,000	\$131,677,000	\$ 81,037,000
1997	\$ 40,136,000	\$171,813,000	\$ 70,895,000
1998	\$ 41,153,000	\$212,966,000	\$ 61,789,000
1999	\$ 45,055,000	\$217,021,000	\$103,489,000
2000	\$ 42,324,000	\$219,521,000	\$157,563,000
2001	\$139,001,000	\$358,522,000	\$203,495,000
2002	\$ 7,601,000	\$ 46,121,000	\$320,927,000

Roxane's income for 2001 was greater than it had been in previous years, due primarily to

Roxane's sale of its palliative care/pain products. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 198:2 - 199:18) The proceeds from the sale of these products were included in Roxane's \$139 million stated income for 2001. (*Id.*, at 212:5 - 214:1) The \$320 million dividend paid to BIC in November 2002 exceeded Roxane's combined income from 1997 through 2001, and was in addition to the \$41 and \$50 million dividends paid to BIC in 1999 and 2000. In total, from 1996 through 2002, Roxane earned approximately \$355 million in income, and paid \$411 million to BIC in dividends. (BIC/BIPI Fauci Exhibit 68 (year-end 1996), at BOEH04600205; BIC/BIPI Fauci Exhibit 69 (year-end 1997), at BOEH04600262; BIC/BIPI Fauci Exhibit 70 (year-end 1998), at BOEH04600306; BIC/BIPI Fauci Exhibit 108 (year-end 1999), at BOEH04600335; BIC/BIPI Fauci Exhibit 72 (year-end 2000 and 2001), at BOEH04600396; BIC/BIPI Fauci Exhibit 67 (year-end 2002), at BOEH04600434; BIC/BIPI Fauci Exhibit 66; BIC/BIPI Fauci Exhibit 71; BIC/BIPI Fauci Exhibit 74) Roxane's retained earnings remained significantly lower than its total liabilities through at least 2004. For example, Roxane's retained earnings in 2003 were approximately \$65 million, compared to total liabilities of \$258 million. (BIC/BIPI Fauci Exhibit 75) Retained earnings in 2004 were approximately \$51 million, compared to total liabilities of \$335 million. (BIC/BIPI Fauci Exhibit 76)

The United States does not dispute that from 1996 through 2005, Roxane's did not deplete funds from its "Capital Stock" of \$19,000, or its "Additional Paid-In Capital" of \$8,735,000. However, the United States disputes that this fact is material to evaluating whether Roxane was sufficiently capitalized at any particular point in time given that Roxane grew in size over time and by 2002, had total liabilities exceeding \$320 million.

37. Roxane always had sufficient working capital to pay for its day-to-day obligations, such as bills, vendors, employees, ingredients and raw materials. (Tab 15, McIntyre Dep. 192-194).

United States' Response: The United States does not dispute that Roxane was able to pay its day-to-day obligations. However, the United States notes that in 2002, Roxane's total liabilities were over five times larger than its stockholders' equity (including retained earnings). Following Roxane's payment of the \$320 million dividend in 2002, Roxane was required to take out a new \$140 million loan from its corporate affiliate, and Roxane's total liabilities increased by almost \$120 million from 2001 to 2002. Roxane's total liabilities continued to exceed its stockholder's equity through at least 2004.

38. Roxane's Board of Directors authorized dividend payments to be made to its parent corporation, BIC, based on the amount of its retained earnings and income. The amount of Roxane's dividend payment would increase when Roxane's income increased. (*Id.* 190-191; (Tab 42, BOEH04600117-21, BOEH04600292-94, BOEH04600326-28, BOEH04600413-15 (Roxane Unanimous Consents))

United States' Response: The United States does not dispute that Roxane's Board of Directors authorized dividend payments to be paid to BIC. The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, Roxane paid no dividends to BIC from 1996 through 1998. Roxane paid dividends in 1999 and 2000 which roughly approximated its total income for those years. In 2002, Roxane deviated from its past practice and paid a dividend of \$320 million, an amount greater than Roxane's total net income for the *preceding five years*. As noted *supra* in the United States' Response to Paragraph 36, this dividend was paid *after* Roxane received its first subpoena from the United States.

Moreover, the \$320 million dividend paid to BIC in November 2002 was inconsistent with Boehringer Ingelheim guidelines. At Boehringer Ingelheim, it was considered appropriate for a subsidiary such as Roxane to pay a dividend if its debt to equity ratio was less than 1.5 to 1. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 210:4 - 211:4) In 2002, following payment of the \$320 million dividend to BIC, Roxane's total liabilities were over *five times*

greater than total equity.

39. Roxane continued to be sufficiently capitalized after all of its dividend payments, as indicated by the company's continued positive retained earnings and positive working capital. (Tab 15, McIntyre Dep. 192; *see also* ¶ 36, *supra*.)

United States' Response: Disputed. As noted *supra*, Roxane's total liabilities were over five times greater than its total equity at year-end 2002, and Roxane's total liabilities continued to greatly exceed total equity through at least 2004. (*See supra* United States' Responses to Paragraphs 36 - 38).

Further answering, prior to 2002, Roxane's debt to equity ratio was consistently less than one (that is, Roxane's liabilities were less than total equity). (*See supra* United States' Response to Paragraph 36). This is consistent with the debt to equity ratios observed at many of Roxane's competitors. Specifically, the United States was able to obtain financial information for six companies Roxane regarded as competitors. Of those six, four companies consistently had debt to equity ratios less than 1.5 to 1. (BIC/BIPI Fauci Exhibit 110 (Declaration of Patrick Ormond), ¶¶ 17 - 19)

Roxane's debt to equity ratio grew to in excess of 5 to 1 only after Roxane paid a \$320 million dividend to BIC in November 2002. Payment of this dividend left Roxane significantly less capitalized than it had been from 1996 through 2001, and significantly less capitalized than many of its competitors. (*See supra* United States' Response to Paragraph 36; BIC/BIPI Fauci Exhibit 110 (Declaration of Patrick Ormond), ¶¶ 17 - 19). Moreover, payment of this dividend was in apparent disregard of Boehringer Ingelheim's guidelines regarding dividends. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 210:4 - 211:4)

40. Roxane also held substantial assets in its own name, such as its manufacturing plant and equipment, inventories, and the rights, title and interest in its line of products. (Tab 44, BOEH02541150-69 at 11-12 (Commentary 1997 Actual); Tab 49, BOEH00147729-58 at 26-27

(2002 Year-End Financial Commentary); Tab 53, BOEH01046045-6092 (Elan Asset Purchase Agreement))

United States' Response: The United States does not dispute that Roxane has held certain assets in its own name, including those identified in this paragraph.

III. The Interactions And Relationships Between Roxane, BIPI And BIC Were Appropriate And Typical Of Normal Parent, Subsidiary And Affiliate Relationships.

(a) Inter-company transactions were conducted on arms-length terms

41. Starting in 1993, BIPI contracted with Roxane to manufacture certain products, including Atrovent UDV. (Tab 15, McIntyre Dep. 80-81)

United States' Response: Undisputed.

42. A 1993 written Contract Manufacturing Agreement provided the terms under which Roxane manufactured products for BIPI. (*Id.* 81, 203-204; Tab 54, McIntyre Ex. 29, BOEH04689322-32 (1993 Contract Manufacturing Agreement) (1993 Contract)) The contract had a ten year renewable term. (Tab 15, McIntyre Dep. 81-82; Tab 54, McIntyre Ex. 29, BOEH04689322-32 at 23 (1993 Contract))

United States' Response: The United States does not dispute that Roxane and BIPI entered into a 1993 contract pursuant to which Roxane manufactured and sold Alupent and Atrovent Solution to BIPI. (Tab 54, at BOEH04689331) Further answering, Roxane manufactured and sold other products to BIPI which were *not* covered by the 1993 contract including, for example, Mobic. (BIC/BIPI Fauci Exhibit 6 (10/19/2004 Tetzner Dep.), at 144:15 - 145:4)

43. In 2005, after the split of Roxane's marketing/sales and manufacturing businesses, BIRI and BIPI entered into a new written manufacturing contract. (Tab 15, McIntyre Dep. 204-205; Tab 55, McIntyre Ex. 30, BOEH04689307-21 (2005 BIRI/BIPI Contract Manufacturing Agreement) (2005 BIRI/BIPI Contract)) At the same time, BIRI and Roxane entered into a written contract manufacturing agreement containing the same terms. (Tab 15, McIntyre Dep. 207-208; Tab 56, McIntyre Ex. 31, BOEH04689293-306 (2005 BIRI/RLI Contract Manufacturing Agreement) (2005 BIRI/RLI Contract)) The 2005 contracts provided that BIPI and RLI would each pay BIRI its cost plus 10% for manufacturing drugs. (Tab 15, McIntyre Dep. 205, 208; Tab 55, McIntyre Ex. 30, BOEH04689307-21 at 15 (2005 BIRI/BIPI Contract); Tab 56, McIntyre Ex. 31, BOEH04689293-306 at 99 (2005 BIRI/RLI Contract))

United States' Response: Undisputed. Further answering, Roxane's 2005 reorganization was at least in part, due to Boehringer Ingelheim's recognition that it operated in the United States with a "variety of legal entities that [did] not necessarily reflect the nature of [its] businesses" and which "often [did] not convey clearly the performance of [its] businesses." (BIC/BIPI Fauci Exhibit 44)

44. BIPI was originally charged a set price per product under the 1993 agreement. (Tab 54, McIntyre Ex. 29, BOEH04689322-32 at 26, 32 (1993 Contract)) In 2001, BIPI began being charged on a "cost-plus" basis. Roxane's costs included ingredient costs, labor and overhead, and then a profit percentage was added to the cost. (Tab 15, McIntyre Dep. 82-86) The profit margin Roxane received on its contract manufacturing services under the cost-plus terms put in place in 2001 was later validated as an arms-length rate by a third-party consultant who performed a study in 2004 of pharmaceutical manufacturing contracts between comparable companies and the profit margins those contracts contained. (*Id.* 87-88, 206-207)

United States' Response: The term "set price per product" is ambiguous as used in this paragraph. Roxane's corporate representative testified that he was unable to determine what price was charged to BIPI under the 1993 contract, but that he believed the price included some margin to Roxane. He did not know the size of the margin. (BIC/BIPI Fauci Exhibit 45 (2/25/2009 McIntyre Dep.), at 84:20 - 85:12) The United States also does not dispute that beginning in or around 2001, Roxane sold Alupent and Atrovent Solution to BIPI on a "cost-plus" basis, and that the price to BIPI included a 2.2% markup. (*Id.*, at 85:13 - 87:22) The United States further admits that in or around 2004, the 2.2% markup was "validated" by "outside consultants." (*Id.*, at 85:13 - 88:14)

45. For a period of time between 1996 and 2001, Roxane licensed a BIPI-developed drug called Viramune, which it marketed and sold as part of its HIV and palliative care specialty line. (*Id.* 156-157) Roxane booked the sales for Viramune and paid BIPI an 11% royalty pursuant to a written licensing agreement. (*Id.* 157, 172-173)

United States' Response: Undisputed.

46. Roxane also licensed a product called Mexilitine from BIPI for a period of time, and

paid an 11% royalty rate pursuant to a written licensing agreement. (Tab 57, BOEH04689278-92 at 285 (1995 BIPI/Roxane Mexilitine License Agreement))

United States' Response: Undisputed.

47. Roxane paid the same 11% royalty for the right to market its generic ipratropium bromide under BIPI's NDA for Atrovent. (Tab 15, McIntyre Dep. 72-73)

United States' Response: Undisputed.

48. The 11% royalty Roxane paid had been previously validated by a third-party consultant as an arms-length amount. (*Id.*)

United States' Response: The United States does not dispute that the 11% royalty rate Roxane paid to BIPI on certain products was the same as the royalty rate paid by BIPI to a Boehringer Ingelheim affiliate in Germany, and that the royalty rate paid by BIPI to its German affiliate was validated by an outside consultant. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 72:13 - 75:7) The paragraph is otherwise denied, and is not supported by the cited authority.

(b) Shared services were appropriately accounted for between the companies.

49. Certain BIPI departments provided shared services at various times, including accounting, tax, legal, IT and contract administration. (Tab 15, McIntyre Dep. 38-41, 48-49; Tab 20, Russillo Dep. 273-274). Roxane was charged back and paid for the value of the services it used. (Tab 15, McIntyre Dep. 34, 37, 40, 49; Tab 20, Russillo Dep. 271-274)

United States' Response: The United States does not dispute that employees at BIPI provided services to other Boehringer Ingelheim entities, including Roxane. For example, Mr. Russillo (who supervised Roxane's multi-source marketing) testified that Roxane's "AWP practices" were reviewed by lawyers acting on behalf of Boehringer Ingelheim. (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 259:12 - 260:10, 280:14 - 281:21) Likewise, Bruce Banks, an in-house attorney employed by BIPI, was a member of a "pricing committee" (comprised of BIPI and Roxane sales and marketing personnel) which reviewed BIPI and Roxane's "pricing strategies." (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 36:18 - 43:1, 91:23 - 94:17)

The United States does not dispute that Roxane was “charged back” for some of these services (including accounting, tax, legal, and IT) on an “accounting basis.” (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 49:15 - 53:9) There is no evidence that Roxane was actually invoiced for these services, however. (*Id.*) Moreover, as noted *supra* in the United States Responses to Paragraph 7, 8, and 14, several BIPI employees played active roles in the marketing and promotion of Roxane’s drugs, including (among others) Mr. King, Mr. Berkle, and Mr. Ciarelli. There is no evidence that Roxane was “charged back” any portion of these employees’ salaries. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 62:16 - 65:9) Likewise, although Mr. Russillo was paid by Ben Venue Labs, he supervised Roxane’s multi-source marketing and there is no evidence Roxane was charged back for any portion of Mr. Russillo’s salary. (*Id.*)

50. At the beginning of each year, each department providing shared services would develop an operating budget and present it for approval to each subsidiary. Based on historical averages, an estimate would be made for how much work (*e.g.*, how many hours for legal services) each entity was predicted to use. Each legal entity was charged at a rate that made sense for that service (*e.g.*, hours for legal work). The estimated work and actual work used by each entity was tracked throughout the year so that by the end of the year, the actual charges for each subsidiary could be reconciled (Tab 15, McIntyre Dep. 51-52)

United States’ Response: Undisputed, except there is no evidence Roxane was charged back for any portion of the salaries of the various BIPI or Ben Venue Labs employees who marketed or promoted Roxane’s products. *See supra* United States Response to Paragraph 49.

51. In addition to shared services, a business unit concept was put in place to coordinate high level strategic oversight of BIPI and Roxane’s common business areas for a period of time before Roxane divested its few brand products. Sheldon Berkle, a BIPI employee and Roxane board member, was designated as Vice-President of the Business Unit. (Tab 1, 1/27/05 Berkle Dep. 63-64; Tab 2, 10/31/08 Berkle Dep. 186-87) In this role, Mr. Berkle provided only strategic oversight, and was not involved in the day-to-day operations of Roxane. (*Id.*)

United States’ Response: The United States does not dispute that in or around 1994,

Boehringer Ingelheim created a business unit including Roxane and BIPI (and later Ben Venue Labs), or that Mr. Berkle was in charge of the Business Unit. (*See supra* the United States' Response to Paragraph 7) The United States disputes, however, that the Business Unit only coordinated "high level strategic oversight" of BIPI and Roxane, and that Mr. Berkle "was not involved in the day-to-day operations of Roxane." In fact, Mr. Berkle (as well as other BIPI employees) was actively involved in Roxane's marketing efforts, including approving marketing plans and proposed AWP's for the Subject Drugs.

Further answering, Mr. Berkle was responsible for directing the efforts of senior personnel in the BIPI and Roxane marketing departments, such as Ed Tupa (then Roxane's Vice President of Sales and Marketing) and Fred Duy (then Roxane's Director of Business Development). (BIC/BIPI Fauci Exhibit 14; BIC/BIPI Fauci Exhibit 19 (11/10/2005 Tupa Dep.), at 52:6 - 52:20; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 53:2 - 54:16) In or around May 1996, Roxane implemented "plans for a restructured business unit including the Marketing, Sales and Business Development Departments" at Roxane and BIPI. (BIC/BIPI Fauci Exhibit 17) Specific changes included that "certain former Roxane and BIPI functions" became "a part of the (BU) Business Unit having responsibilities for activities at both Roxane and BIPI." (*Id.*) These functions included "Forecasting, Market Research, Technical Support, Project Management, Managed Care, Sales Support Business Development and Business Intelligence" as well as "the BU Sales Training, BU Trade Relations, the BU Contracts functions." (*Id.*) Additional changes to the Business Unit's management were announced in an October 1998 Employee Bulletin, including that Jim King began to supervise the BIPI/Roxane branded sales force, and BIPI and Roxane contracting were combined into a "single organization." (BIC/BIPI Fauci Exhibit 18) In addition, Christine Ferrara (a BIPI employee) began to "manage a unified

pricing process for the Business Unit.” (*Id.*; BIC/BIPI Fauci Exhibit 15 (10/31/2009 Berkle Dep.), at 254:22 - 255:2) In that capacity, Ms. Ferrara reported to Gregg Ciarelli (also a BIPI employee). (BIC/BIPI Fauci Exhibit 18; BIC/BIPI Fauci Exhibit 51 (6/26/2002 Ciarelli Dep.), at 9:17 - 10:11, 13:14 - 14:7, 50:6 - 50:13) These management changes were announced publicly in a January 1999 “news release.” (BIC/BIPI Fauci Exhibit 77) Moreover, a 1999 Roxane organizational chart confirms that several BIPI employees (including Mr. Berkle, Mr. King, Mr. Ciarelli, Mr. Leonetti and others) had responsibilities for marketing and/or promoting Roxane’s drugs. (BIC/BIPI Fauci Exhibit 50) The organizational changes were also described at an October 1998 meeting of the BIC Board of Directors. (BIC/BIPI Fauci Exhibit 16, at BICJURIS0236). Minutes from that states that “sales and marketing for branded generics will report to BIPI counterparts.” (*Id.*)

Consistent with the management structure described in the Business Unit’s organizational charts, news releases and employee bulletins, Roxane and BIPI shared a common “Pricing Policy and Procedure” for BIPI products and Roxane branded generic products (including Subject Drugs Roxicodone, Oramorph SR, and Roxanol). (BIC/BIPI Fauci Exhibit 78; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 214:22 - 215:19) Pursuant to the Pricing Policy and Procedure, recommended prices for Roxane’s branded generic products (including proposed WACs and AWP) required approval first by a pricing committee, comprised jointly of Roxane and BIPI personnel, and then by the “Executive Vice President, Ethical Pharmaceuticals” (Mr. Berkle) and the “President and CEO, Boehringer Ingelheim Corporation” (Mr. Gerstenberg). (BIC/BIPI Fauci Exhibit 78; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 219:20 - 222:15, 343:15 - 344:22) The August 2000 launch of Roxane’s 15 and 30 mg Roxicodone tablets (NDCs 00054-4568025 and 00054-4665025) demonstrates how this procedure operated in practice, and

reveals the extent of BIPI's involvement in setting inflated AWP's for Roxane's products.

On August 12, 2000, Mr. Duy emailed the launch plan and "pricing proposal" for the 15 and 30 mg Roxicodone tablets to Mr. Berkle and several other BIPI employees. (BIC/BIPI Fauci Exhibit 80; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 169:12 - 177:5) This was consistent with Mr. Duy's general practice. (BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 54:9 - 54:16) The launch plan recommended setting AWP's twice as high as WAC's in order to create "favorable retail reimbursement" and ensure that providers stocked the products. (BIC/BIPI Fauci Exhibit 80, at Shaffer 001480, 001486, 001516; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 181:9 - 183:15) No fewer than five BIPI employees were involved in the decision to approve the Roxicodone pricing and launch plan. For example, on or about August 14, Ms. Ferrara (a BIPI employee who managed the Business Unit's pricing process) questioned the calculation of "the average spread to [p]harmacy," causing Mr. Duy to adjust the proposal accordingly. (BIC/BIPI Fauci Exhibit 81) On or about August 15, Mr. Berkle asked Ms. Ferrara whether it was possible to "speed up" the price review process (BIC/BIPI Fauci Exhibit 82), and in the following days several BIPI employees reviewed and endorsed the launch plan including, Mr. Ciarelli, Mr. Leonetti, Mr. King and David Laros (BIC/BIPI Fauci Exhibit 83; BIC/BIPI Fauci Exhibit 84; BIC/BIPI Fauci Exhibit 85; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 196:1 - 198:6, 202:18 - 203:19; BIC/BIPI Fauci Exhibit 107) Mr. Leonetti commented on the "very favorable pharmacy spread" and asked if First Data Bank would publish these prices. Mr. Leonetti concluded, "I guess it really does not matter if it's published as long as the pharmacist knows the true WAC." (BIC/BIPI Fauci Exhibit 83, at BOEH00236099)

On or about August 22, 2000, the pricing committee (including BIPI employees Ferrara,

Ciarelli, Leonetti and King) formally recommended that Mr. Berkle and Mr. Gerstenberg approve the pricing for the Roxicodone products. (BIC/BIPI Fauci Exhibit 86) The Pricing Committee described the proposed AWP as “compatible with the reimbursement model that drives retailer profit.” (*Id.*) Based in part on the committee’s recommendation, Mr. Berkle and Mr. Gerstenberg approved the launch plan and proposed pricing for the Roxicodone products. (BIC/BIPI Fauci Exhibit 87; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 231:19 - 236:9, 254:14 - 256:15, 265:9 - 266:4, 337:8 - 339:16, 341:19 - 344:22) As noted *supra*, Mr. Berkle was employed by BIPI, not Roxane (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 53:1 - 53:18), and the Pricing Policy and Procedure specifically provided that the prices be approved by the *President and CEO, Boehringer Ingelheim Corporation.*” (BIC/BIPI Fauci Exhibit 78) (emphasis supplied), indicating that Mr. Gerstenberg approved the prices in his role as President and CEO of BIC.

A similar approval process was followed for pricing on several other Roxane drugs. (*See, e.g.,* BIC/BIPI Fauci Exhibit 88; BIC/BIPI Fauci Exhibit 89; BIC/BIPI Fauci Exhibit 90; BIC/BIPI Fauci Exhibit 91)

IV. Roxane Controlled Its Day-to-Day Business Operations, Including The Pricing And Marketing Of Its Products.

(a) Marketing and Pricing of Multi-source Generic Products

52. Roxane had its own marketing and sales departments which were responsible for promoting its products. (Tab 2, 10/31/08 Berkle Dep. 324; Tab 22, 8/5/08 Shaffer Dep. 380; Tab 9, 11/18/05 Feldman Dep. 76; Tab 1, 1/27/05 Berkle Dep. 25; Tab 58, D0530608 (2003 Multisource Sales & Marketing Organizational Chart); Tab 59, RLI-ORG00000080 (1996 Budget Organizational Chart); Tab 60, RLI-ORG00000017 (Jan. 1998 Organizational Chart))

United States’ Response: Disputed. As discussed *supra* in the United States Responses to Paragraphs 7, 8, 14 and 51, BIPI and BIC employees played important roles in marketing

Roxane's products, including by approving marketing strategies and prices.

53. Judy Waterer began as Roxane's Manager for Multisource Program Development in 1996. In this position, Waterer was responsible for Roxane's multi-source marketing activities, including launches, training sales representatives, advertising, and pricing. (Tab 26, 10/24/01 Waterer Dep. 31-34) In the early 2000s, Lesli Paoletti, a member of the marketing department, took over many of these responsibilities from Ms. Waterer. (Tab 18, 7/26/07 Paoletti Dep. 15-16; Tab 29, 5/9/07 Waterer Dep. 38, 64-65; Tab 29, 5/10/07 Waterer Dep. 282-283)

United States' Response: The United States does not dispute that Ms. Waterer and later Ms.

Paoletti were involved in "Roxane's multi-source marketing activities." The United States disputes this paragraph, however, to the extent it implies that Ms. Waterer and Ms. Paoletti were solely responsible for these activities, or that BIC and/or BIPI were not actively involved in the conduct for which the United States is seeking damages.

Ms. Waterer reported first to Ed Tupa and then to Tom Russillo. (BIC/BIPI Fauci Exhibit 11 (10/24/2001 Waterer Dep.), at 34:8 - 36:3, 54:9 - 55:2, 57:8 - 57:18) During Mr. Tupa's tenure as Roxane's Vice President of Marketing, Boehringer Ingelheim personnel were involved in decisions to approve marketing plans and prices for Roxane's multi-source drugs. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.), at 35:25 - 38:4; BIC/BIPI Fauci Exhibit 19 (11/10/2005 Tupa Dep.), at 52:17 - 53:10) For example, several BIPI employees met with Roxane personnel (including Mr. Tupa) in January 1996 to discuss marketing strategies for ipratropium bromide. (BIC/BIPI Fauci Exhibit 24, at RLI-AWP-00299558) Minutes from this meeting reflect a discussion of "Medicare reimbursement" and agreement that the AWP for ipratropium bromide should be set at 10% below Atrovent's AWP. (*Id.*) The ipratropium bromide launch plan explained that this pricing structure was used to create an attractive spread between WAC and AWP and thereby "entice" accounts to switch from the brand name to the generic product. (BIC/BIPI Fauci Exhibit 21, at ROX-TX 01344) Mr. Tupa testified that BIPI personnel,

including Mr. Berkle, were involved in the decision to approve the ipratropium bromide marketing plan. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.), at 36:15 - 37:17)

Mr. Russillo testified that he reported to Mr. Gerstenberg “in his role as president and CEO of BIC.” (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 204:1 - 204:7, 206:17 - 207:2, 221:22 - 223:5) Mr. Russillo consulted with BIC and/or BIPI personnel, including members of the pricing committee, on pricing issues that were regarded as “sensitive” or likely to raise “legal” or “government” issues. (BIC/BIPI Fauci Exhibit 92, at BOEH01311860; BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 98:1 - 98:16) For example, in or around July 2000, Mr. Russillo was involved in the decision to raise the AWP’s on Roxane’s furosemide products by up as much as 300%. Mr. Russillo testified that as of at least 1999, he and members of BIC and BIPI’s senior management knew the government was scrutinizing AWP’s and therefore regarded any decision to raise AWP’s as “sensitive” and requiring BIC’s approval. (*Id.*, at 98:9 - 99:7, 179:22 - 180:16 (“The mood at Boehringer Ingelheim was the same as mine. It was very sensitive to AWP changes”); BIC/BIPI Fauci Exhibit 58 (11/28/2005 Waterer Dep.), at 48:19 - 51:5)

Nonetheless, Mr. Russillo was prepared to “champion” and “support” the Furosemide AWP increase and take the proposal “up the line.” (BIC/BIPI Fauci Exhibit 93; BIC/BIPI Fauci Exhibit 94) On July 7, 2000, Mr. Russillo advised Robert Sykora (a BIPI employee who testified his primary responsibilities were for Roxane) that “[t]o get the approval we need from Connecticut” we “need some ‘hard’ info” about competitors’ AWP’s. (BIC/BIPI Fauci Exhibit 95) As noted *supra*, Mr. Russillo testified that at Roxane, “Connecticut” meant Boehringer Ingelheim. (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 36:5 - 36:22)

On July 26, 2000, Mr. Sykora submitted a “sales justification” memorandum and, shortly

thereafter, Mr. Russillo received the “official okay to implement the furosemide price changes.” (BIC/BIPI Fauci Exhibit 96) Mr. Russillo testified that he endorsed the proposed AWP increase only after learning over the course of “many conversations” that Mr. Gerstenberg supported raising Roxane’s AWP’s to match competitors. (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 172:18 - 174:3, 192:11 - 194:3 (“Once I had established Werner Gerstenberg’s position on this, I would have implemented it”), 222:21 - 223:1)

In addition, other BIPI employees recommended marketing strategies for Roxane’s multi-source drugs, including to set inflated AWP’s. For example, James Rowenhorst was employed by BIPI in various positions, including as “Manager of Reimbursements.” (BIC/BIPI Fauci Exhibit 54 (4/3/2003 Rowenhorst Dep.), at 27:10 - 27:20) Although Mr. Rowenhorst was employed by BIPI, he testified that he “was involved in working with Roxane to ensure that reimbursement channels were available for the sale of our products if there seemed to be any reimbursement obstacles in the marketplace.” (*Id.*, at 71:18 - 72:3, 203:1 - 203:15) In June 2000, Mr. Rowenhorst circulated an email including a Wall Street Journal article entitled “Medicare Plans Major Overhaul, Targets Massive Overpayments.” (BIC/BIPI Fauci Exhibit 97) Although the article specifically noted that “State and federal officials believe that some drug companies are reporting artificially inflated AWP’s to industry guides that are used for government-reimbursement purposes,” Mr. Rowenhorst recommended that Roxane continue to “focus on a higher AWP and WAC” as a way to keep competitive with Dey Laboratories for sales of several products, including ipratropium bromide. (*Id.*)

54. Roxane’s multi-source marketing department recommended the initial launch prices, including AWP, WAC, and direct price for Roxane’s generic drugs. The marketing department was also responsible for developing and recommending changes to these prices for Roxane’s generic drugs. In coordination with the contracts department, the marketing department developed pricing guidelines that established the range of contract prices that could be offered to

customers and would assist in developing prices for bids outside of the pre-established grid. (Tab 27, 4/1/03 Waterer Dep. 517-518; Tab 29, 5/11/07 Waterer Dep. 566-567; Tab 31, 12/12/08 Waterer Dep. 47-49; Tab 18, 7/26/07 Paoletti Dep. 110-111; Tab 7, 6/25/02 Feldman Dep. 48, 56, 79-80; Tab 9, 11/18/05 Feldman Dep. 49-50; Tab 30, 7/24/07 Waterer Dep. 869-871; Tab 19, 10/11/05 Powers Dep. 51-52; Tab 16, 9/20/05 Paoletti Dep. 32)

United States' Response: The United States does not dispute that employees in Roxane's multi-source marketing department, including Ms. Waterer and Ms. Paoletti, recommended initial launch prices for some of Roxane's multi-source drugs. The United States disputes this paragraph, however, to the extent it implies that Ms. Waterer and Ms. Paoletti were exclusively responsible for these activities, or that BIC and/or BIPI were not actively involved in the conduct for which the United States is seeking damages. (*See supra* United States' Responses to Paragraphs 7, 8, 14, 51 and 53)

55. The marketing department's pricing recommendations were circulated to various Roxane employees for information and sign-off purposes. The positions and particular individuals included changed over time, but generally included some combination of the product manager, director of multi-source marketing, a member of the finance department, a member of the contracts department, a member of the sales department, and someone in senior management at Roxane, such as Roxane's Vice-President of Sales and Marketing. Examples of Roxane employees in those positions include Lesli Paoletti, Judy Waterer, John Swartz, John Powers, Rich Feldman, and Ed Tupa. (Tab 17, 11/30/05 Paoletti Dep. 16-17, 90-91; Tab 28, 11/28/05 Waterer Dep. 168 (marketing would recommend the pricing and it would get routed and approved by management); Tab 26, 10/24/01 Waterer Dep. 34-38 (price routing forms included marketing management, sales management, contracts management, and sometimes member of senior management, such as Gerald Wojta, President of Roxane); Tab 29, 5/11/07 Waterer Dep. 602-603, 619-621, 624) Other than being circulated to this core set of Roxane employees, prices for Roxane's multi-source drugs never went to a formal pricing committee for approval. (Tab 20, Russillo Dep. 147-148)

United States' Response: The United States does not dispute that pricing recommendations for Roxane's multi-source products were circulated among Ms. Paoletti, Ms. Waterer, Mr. Swartz, Mr. Powers, Mr. Feldman and Mr. Tupa. The United States disputes this paragraph, however, to the extent it implies that this group of employees was exclusively responsible for pricing and marketing Roxane's multi-source products, or that BIC and/or BIPI were not actively involved in

the conduct for which the United States is seeking damages. (*See supra* United States' Responses to Paragraphs 7, 8, 14, 51 and 53) Further answering, the pricing committee became involved with multi-source pricing when "legal" or "government" issues were implicated. (BIC/BIPI Fauci Exhibit 92, at BOEH01311860)

56. Until 1998, Ms. Waterer reported to Ed Tupa, Vice-President of Marketing at Roxane. (Tab 26, 10/24/01 Waterer Dep. 57) While Mr. Tupa had a functional reporting relationship to Mr. Berkle, Vice President of the Business Unit Ethical Pharmaceuticals, Mr. Tupa led Roxane's marketing department, with Ms. Waterer handling the day-to-day marketing and pricing activities for Roxane's products. Mr. Berkle's role was limited to very high level strategic oversight. (Tab 26, 10/24/01 Waterer Dep. 31-34; Tab 2, 10/31/08 Berkle Dep. 50-51; *id.* 76 ("I was not involved in the day-to-day operations of Roxane or in basically how they set their prices in general or how they marketed their generic drugs"); *id.* 125 ("In general I've said to you before that I really did not get involved in the details of pricing for the generic products within the Roxane line"); Tab 61, 10/31/08 Berkle Dep. Ex. 5, RLI-AWP-00162482-84 at 83 (5/3/96 Roxane Sales and Marketing Reorganization Announcement and Organizational Chart) (1996 Reorganization Announcement) ("The Roxane Marketing & Sales Department will be led by Mr. Edward Tupa, who currently has this responsibility."); Tab 62, RLI-ORG000000068 (Jan. 1998 Organigram); Tab 59, RLIORG000000080 (1996 Budget Organizational Chart))

United States' Response: The United States does not dispute that Ms. Waterer reported to Mr. Tupa for a period of time, or that Mr. Tupa "functionally" reported to Mr. Berkle. The United States disputes, however, that Mr. Berkle's "role was limited to very high level strategic oversight." Further answering, Mr. Berkle had detailed involvement in the marketing of Roxane's branded generic products, including approving marketing plans and pricing. (*See infra* United States' Response to Paragraph 51) Mr. Berkle also was involved in Roxane's marketing of multi-source products, including reviewing proposed marketing strategies, (*see* United States' Responses to Paragraphs 7 and 53), and reviewing bids to important customers such as Premier and Cardinal Health. (*See, e.g.*, BIC/BIPI Fauci Exhibit 73; BIC/BIPI Fauci Exhibit 42) In addition, other BIPI employees (including Mr. Rowenhorst) participated in marketing decisions for Roxane's multi-source products. (BIC/BIPI Fauci Exhibit 97)

57. Ed Tupa left his position as Vice President of Marketing in October 1998. Tom Russillo, who was the President of another BIC subsidiary, Ben Venue Laboratories, Inc. (“BVL”), took on the additional position of head of Multisource Marketing for Roxane at that time. (Tab 63, 10/31/08 Berkle Ex. 27 RLI-AWP-00161738-40 (10/23/98 Reorganization Memo); Tab 20, Russillo Dep. 23-26; Tab 32, RLI-ORG00000016 (Jan. 1998 Organigram)) Mr. Russillo reported to Werner Gerstenberg. (Tab 20, Russillo Dep. 29)

United States’ Response: Undisputed. Further answering, Mr. Russillo’s “responsibility for Roxane’s multi-source business [wa]s not well recognized in the industry.” (BIC/BIPI Fauci Exhibit 98)

58. Ms. Waterer and others in the Roxane multi-source marketing department began reporting to Mr. Russillo in this new role. (Tab 63, 10/31/08 Berkle Ex. 27 at RLI-AWP-00161738-40 (10/23/98 Memo); Tab 26, 10/24/01 Waterer Dep. 57; Tab 20, Russillo Dep. 49-50, 53-54; Tab 58, D0530608 (2003 Multisource Sales & Marketing Organizational Chart))

United States’ Response: Undisputed. Further answering, *see supra* United States’ Response to Paragraphs 7, 8, 14, 51 and 53.

59. Mr. Russillo had worked in the generic pharmaceutical business for many years and Ben Venue’s generic sales division, Bedford Laboratories, was very successful in the market. Thus, Mr. Russillo had extensive experience and expertise in marketing and selling generic drugs that he could bring to bear to help build Roxane’s generic business. (Tab 20, Russillo Dep. 26, 202-203)

United States’ Response: Undisputed. Further answering, *see supra* United States’ Response to Paragraphs 7, 8, 14, 51 and 53.

60. Mr. Russillo “ultimately managed” the pricing approval process for Roxane’s multi-source drugs from late 1998 forward. (*Id.* 53-54, 286) Ms. Waterer and the Roxane marketing department, however, continued to be responsible on a day to day basis for setting the AWP’s for multi-source products. (*Id.* 49-50, 54 (“For the most part, I would not be personally involved. Judy would propose an AWP; and for the most part, I would have approved it.”); Tab 26, 10/24/01 Waterer Dep. 57, 168-170)).

United States’ Response: The United States disputes this paragraph to the extent it implies that BIC and/or BIPI were not involved in the conduct for which the United States is seeking damages. Further answering, *see infra* United States’ Responses to Paragraphs 7, 8, 14, 51 and

53.

61. Although Mr. Russillo was able to approve or disapprove AWP and price recommendations without further routing to other Roxane employees, Ms. Waterer continued to circulate price proposals to key Roxane employees. (Tab 29, 5/11/07 Waterer Dep. 596; *see also, e.g.*, Tab 64, RLI-AWP-00559612 (Feb. 19, 2002 Price Approval form); Tab 65, RLI-AWP-00081519 (April 1, 2002 Price Approval form); Tab 66, RLI-AWP-00083025-30 (Feb. 20, 2003 Price Approval form); Tab 67, BOEH01140848 (May 28, 2003 Price Approval form); Tab 68, RLI-AWP-00082794-09 (June 4, 2003 Price Approval form); Tab 69, RLI-AWP-00081645-51 (July 2, 2003 Price Approval Email Chain))

United States' Response: The United States disputes that Mr. Russillo approved raising Roxane's AWP's on his own. Mr. Russillo testified that he only supported raising the AWP's for furosemide *after* establishing Mr. Gerstenberg's position. (*See infra* United States' Response to Paragraph 53; BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 172:18 - 174:3, 192:11 - 194:3, 222:21 - 223:1) Further answering, Mr. Russillo made clear that Boehringer Ingelheim's approval was required prior to raising the furosemide AWP's. (*See, e.g.*, BIC/BIPI Fauci Exhibit 95)

62. Mr. Russillo generally did have to seek further approval from his superiors regarding Roxane multi-source prices. Rather, at his discretion, he may have consulted Werner Gerstenberg, who was the President of Roxane. (Tab 20, Russillo Dep. 98)

United States' Response: Disputed. Mr. Russillo testified that he only supported raising the furosemide AWP's *after* establishing Mr. Gerstenberg's position. (*See infra* United States' Response to Paragraph 53; BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 172:18 - 174:3, 192:11 - 194:3, 222:21 - 223:1) Further answering, Mr. Russillo made clear that Boehringer Ingelheim's approval was required. (*See, e.g.*, BIC/BIPI Fauci Exhibit 95)

63. After Roxane's management signed-off on initial prices or price changes for Roxane's generic products, someone from Roxane's marketing or trade relations departments would report the pricing information to third party compendia, such as First Data Bank. (Tab 27, 4/1/03 Waterer Dep. 501-502, 581; Tab 29, 5/11/07 Waterer Dep. 682-86; Tab 17, 11/30/05 Paoletti Dep. 47-49; Tab 70, 5/10/07 Waterer Dep. Ex. 24 (Red Book 13858-59); Tab 71, 5/10/07 Waterer Dep. Ex. 25 (Red Book 13860-13864); Tab 72, 5/10/07 Waterer Dep. Ex.

26(Red Book 13865-13867); Tab 73, 5/10/07 Waterer Dep. Ex. 27 (Red Book 13868-13870); Tab 74, 5/10/07 Waterer Dep. Ex. 29 (Red Book 13969-13971); Tab 75, 5/10/07 Waterer Dep. Ex. 30 (Red Book 13972-13974); Tab 76, 5/10/07 Waterer Dep. Ex. 31 (Red Book 13975-76); Tab 77, 5/10/07 Waterer Dep. Ex. 34 (Red Book 14071-14083); Tab 78, 5/10/07 Waterer Dep. Ex. 35 (Red Book 14084-14085); Tab 79, 5/10/07 Waterer Dep. Ex. 42 (Red Book 14185-14186); Tab 80, 5/10/07 Waterer Dep. Ex. 47 (Red Book 14205-14206); Tab 81, 11/17/04 Feldman Dep. Ex. 93 TXEX00520)

United States' Response: The United States disputes the first sentence of this paragraph to the extent it implies that BIC and/or BIPI did not actively participate in decisions to approve inflated AWP's for Roxane's drugs. The United States does not dispute that employees in the marketing and Trade Relations departments reported pricing information for Roxane's multi-source products (including AWP's) to third party pricing compendia. Specifically, prior to 2001, the Trade Relations Department was responsible for reporting AWP's to third party pricing compendia; after 2001, Ms. Paoletti in the marketing department took over this responsibility. (BIC/BIPI Fauci Exhibit 99 (11/30/2005 Paoletti Dep.), at 48:15 - 50:9; BIC/BIPI Fauci Exhibit 100 (9/20/2005 Paoletti Dep.), at 81:15 - 82:24)

Further answering, prior to 2001, the Trade Relations Department was responsible for *both* Roxane and BIPI products. (*See, e.g.*, BIC/BIPI Fauci Exhibit 34 (11/17/2004 Feldman Dep.), at 108:24 - 109:25; BIC/BIPI Fauci Exhibit 35 (1/25/2005 Dawn Gordon Dep.), at 19:14 - 21:9; BIC/BIPI Fauci Exhibit 37 (12/2/2005 Mike Doan Dep.), at 43:19 - 44:8; BIC/BIPI Fauci Exhibit 38 (11/22/2005 Anthony Tavoraro Dep.), at 57:17 - 59:1) As the Executive Director of the Trade Relations Department, Richard Feldman reported AWP's to pricing compendia for both Roxane and BIPI products. (*See* BIC/BIPI Fauci Exhibit 105)

Moreover, BIPI personnel were responsible for reporting AWP's to the pricing compendia for Roxane's branded and branded generic products. (BIC/BIPI Fauci Exhibit 52 (7/25/2007 Ciarelli Dep.), at 22:10 - 24:10, 28:17 - 29:4, 49:17 - 49:21)

64. At times, Roxane received requests from third party compendia to verify its reported AWP's and WACs. Roxane's marketing department was responsible for reviewing the information and communicating any changes or corrections to the compendia. (Tab 29, 5/10/07 Waterer Dep. 455-458; Tab 18, 7/26/07 Paoletti Dep. 195-197; Tab 82, 5/9/07 Waterer Dep. Ex. 32 (Red Book 13977-14065))

United States' Response: Undisputed.

65. Roxane had National Account Managers ("NAMs") who handled day-to-day marketing and sales interactions with Roxane's customers, including wholesalers and chains. (Tab 23, Sykora Dep. 200-202; Tab 8, 11/17/04 Feldman Dep. 86-87)

United States' Response: The United States does not dispute that NAMs promoted Roxane's products. Further answering, the NAMs were in the Trade Relations Group which, prior to 2001, had responsibility for promoting both Roxane and BIPI products. (*See, e.g.*, BIC/BIPI Fauci Exhibit 34 (11/17/2004 Feldman Dep.), at 108:24 - 109:25; BIC/BIPI Fauci Exhibit 35 (1/25/2005 Gordon Dep.), at 19:14 - 21:9; BIC/BIPI Fauci Exhibit 37 (12/2/2005 Doan Dep.), at 43:19 - 44:8; BIC/BIPI Fauci Exhibit 38 (11/22/2005 Tavolaro Dep.), at 57:17 - 59:1)

66. Based on their knowledge of market conditions, NAMs would provide the marketing department with recommendations for price changes as the competitive landscape for certain drugs changed. The marketing department would compile relevant information and develop a final pricing recommendation. (Tab 23, Sykora Dep. at 76-77; Tab 28, 11/28/05 Waterer Dep. at 32-35)

United States' Response: Undisputed. Further answering, *see supra* United States Response to Paragraph 65.

67. In June 1996, Roxane launched ipratropium bromide, a generic version of BIPI's brand product Atrovent. (Tab 26, 10/24/01 Waterer Dep. 38-39; Tab 29, 5/10/07 Waterer Dep. 292-294; Tab 25, 10/18/05 Via Dep. 61)

United States' Response: Undisputed.

68. Tom Via, a Roxane marketing employee, developed the marketing plan for ipratropium bromide. As part of that process, Mr. Via and Ed Tupa, Roxane's Vice President of Sales and Marketing set the AWP, WAC, and direct prices for ipratropium bromide at the product's launch. (Tab 25, 10/18/05 Via Dep. 154-155, 157, 163-165) The AWP's for Roxane's ipratropium bromide did not change from launch until the product was discontinued in 2004.

(Tab 83, Roxane's Second Supp. Objections and Answers to the Commonwealth's First Set of Interrogatories (7/18/07) at 3)

United States' Response: The United States does not dispute that Mr. Via and Mr. Tupa participated in the development of the ipratropium bromide marketing plan. The United States disputes this paragraph to the extent it implies that Mr. Via and Mr. Tupa were exclusively responsible for the ipratropium bromide marketing plan. As noted *supra* in the United States' Responses to Paragraphs 7 and 53, Mr. Tupa testified that Mr. Berkle was involved in the decision to approve the ipratropium bromide marketing plan. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.), at 36:15 - 37:17) Moreover, BIPI employees met with Roxane employees regarding marketing strategies for ipratropium bromide, including at a January 1996 meeting where it was agreed that the AWP for ipratropium bromide would be set at 10% less than Atrovent's AWP. (BIC/BIPI Fauci Exhibit 24, at RLI-AWP-00299558)

69. Because BIPI had experience in the respiratory product market from its sales of Atrovent, as Roxane prepared to launch its generic product, BIPI shared information and expertise on a high-level about the respiratory drug market and current market conditions. No one from BIPI was involved in marketing details or price setting for Roxane's ipratropium bromide. (Tab 1, 1/27/05 Berkle Dep. 28, 38, 72-73)

United States' Response: Disputed. Further answering, *see supra* United States' Responses to Paragraphs 7, 53 and 68.

70. In 2000, Roxane sought to change the AWP on one of its multi-source products, furosemide, due to customer complaints that it was out of line with the AWP for that drug in the rest of the market. (Tab 29 5/9/07 Waterer Dep. 75-76) Roxane's marketing and sales teams compiled supporting documentation for the AWP change, and the marketing department developed a price change recommendation for Mr. Russillo's review. (Tab 17, 11/30/05 Paoletti Dep. 141-145; Tab 29, 5/9/07 Waterer Dep. 201-202)

United States' Response: Undisputed, except that when Mr. Russillo requested supporting documentation for the furosemide price change, he advised Mr. Sykora that "[t]o get the approval we need from Connecticut," we "need some 'hard' info" about competitors' AWP. (BIC/BIPI

Fauci Exhibit 95) Mr. Russillo testified that “Ridgefield, Connecticut, to me meant BIPI.” (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 36:5 - 36:22) Other emails sent by Ms. Waterer describe Mr. Russillo as willing to “champion” or “support” the furosemide AWP increase, indicating that approval from Mr. Russillo’s superior at Boehringer Ingelheim was required. (BIC/BIPI Fauci Exhibit 94)

71. Mr. Russillo approved the marketing department’s recommendation to increase furosemide’s AWP. While Mr. Russillo did not believe he sought further approval for the furosemide price increase, he explained that if he had, he would have discussed the price change with Werner Gerstenberg, in his role as President and COO of Roxane. (Tab 20 Russillo Dep. 167-168, 174-75, 178-179, 191-192)

United States’ Response: Disputed. As noted *supra*, Mr. Russillo testified that he reported to Mr. Gerstenberg “in his role as president and CEO of BIC.” (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 29:8 - 30:10, 204:1 - 204:7, 205:19 - 207:2) The evidence supports the conclusion that Mr. Russillo reported to Mr. Gerstenberg as CEO of BIC for several reasons. First, Mr. Russillo testified that he reported to Mr. Gerstenberg both when Mr. Russillo was acting as the Chief Operating Officer at Ben Venue Labs and when he was supervising Roxane’s multi-source marketing. (*Id.*) Mr. Russillo did so even though there is no evidence that Mr. Gerstenberg was an officer of Ben Venue Labs. Second, Mr. Russillo continued to report to Mr. Gerstenberg through 2003, *after* Mr. Gerstenberg had stepped down as President of Roxane, but when Mr. Gerstenberg was still serving as President of BIC. (*Id.*) Third, Mr. Russillo testified that he reported to Martin Carroll as President of BIC after Mr. Carroll replaced Mr. Gerstenberg in that role, even though Mr. Carroll was not an officer at Roxane. (*Id.*; *see also* BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 31:11 - 32:10)

(b) Marketing of Brand and Branded Generic Products

72. Until the 2000-2001 timeframe, Roxane sold a small line of brand and branded

generic drugs in addition to its main line of multi-source generic drugs. These drugs included HIV and palliative care/pain products. (Tab 7, 6/25/02 Feldman Dep. 174; Tab 2, 10/31/08 Berkle Dep. 30-31; Tab 21, 5/21/08 Shaffer Dep. 54-55; Tab 84, RLI-ORG 00000083 (1999 Roxane Sales Org. Chart))

United States' Response: The United States disputes that Roxane's brand and branded generic drugs constituted a "small line" of products. According to a Roxane "Position Paper" from 1999, Roxane's "largest seller" at that time was Viramune®, an HIV/AIDS drug assigned to Roxane by BIPI, which accounted for \$106 million of Roxane's expected \$412 million in third-party net sales for 1999. (BIC/BIPI Fauci Exhibit 60, at BOEH02601796) The Position Paper described Roxane's "branded generics" in the pain/palliative care area as "important contributors to its sales and profits." (*Id.*) The Position Paper specifically noted that Oramorph SR, Roxicodone and Roxanol (all branded generic products and all Subject Drugs) collectively produced sales of \$40 million in 1999. (*Id.*)

73. Branded generic drugs are generic drugs that have been given proprietary names beyond the chemical formulation (such as Roxicodone, Roxicet or Roxanol) and are marketed to physicians in the same manner as brand products. (Tab 2, 10/31/08 Berkle Dep. 31; Tab 3, 12/12/08 Carr Hall Dep. 74-75)

United States' Response: The United States does not dispute that Roxane regarded its branded generic products as drugs with proprietary names, and that Roxane marketed those drugs according to a branded marketing strategy.

74. Roxicodone, Oramorph SR, and Roxanol -- three of the drugs at issue in this case -- were part of Roxane's branded generic palliative care line. (*See* United States' First Amended Complaint at ¶ 58; Tab 21, 5/21/08 Shaffer Dep. 55)

United States' Response: Undisputed. *See supra* United States' Response to Paragraph 72.

75. Roxane had its own marketing staff dedicated to promoting its brand and branded generic products that was separate from its multi-source marketing team. The marketing staff reported to Gary Ellexson, Executive Director of Marketing RLI Brands. Mr. Ellexson reported to Ed Tupa, Vice President of Marketing at Roxane, until he left the company in October 1998. The marketing staff product managers were responsible for launching new products and Ed Tupa

was involved in developing pricing for the brand/branded generic products. (Tab 29, 5/10/07 Waterer Dep. 254-56; Tab 5, 7/25/07 Ciarelli 33-34; Tab 4, 6/26/02 Ciarelli Dep. 30-31, 98; Tab 29, 5/10/07 Waterer Dep. 304; Tab 25, 10/18/05 Via Dep. 42-44, 50; Tab 21, 5/21/08 Shaffer Dep. 50; Tab 85, 5/21/08 Shaffer Dep. Ex. 10 (Oramorph SR Price Increase))

United States' Response: The United States does not dispute that Roxane employed a palliative cares field sales force or that Mr. Tupa and Mr. Ellexson had responsibility for promoting Roxane's branded generic drugs. The United States disputes this paragraph to the extent it implies that BIC and/or BIPI were not actively involved in the conduct for which the United States is seeking damages. As noted *supra* in the United States' Response to Paragraph 51, BIPI employees' involvement in the approval of marketing strategies and pricing for Roxane's branded generic products was both formal and pervasive. Roxane and BIPI shared a common "Pricing Policy and Procedure" for BIPI's products and Roxane's branded generic products, which required approval of a proposed AWP first by a joint Roxane/BIPi pricing committee and then by the "Executive Vice President, Ethical Pharmaceuticals" (Mr. Berkle) and the "President and CEO, Boehringer Ingelheim Corporation" (Mr. Gerstenberg). (BIC/BIPi Fauci Exhibit 78; BIC/BIPi Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 214:22 - 215:19) No fewer than five BIPI employees were involved in the decision to approve WAC and AWP pricing for Roxane's August 2000 launch of Roxicodone. (*See supra* United States' Response to Paragraph 51)

Moreover, even though Roxane had a palliative care sales force, the National Account Managers in the Trade Relations Group also had responsibility for promoting branded generic products. (*See, e.g.*, BIC/BIPi Fauci Exhibit 101 (11/4/2005 Gordon Dep.), at 55:21 - 57:6; BIC/BIPi Fauci Exhibit 102 (10/18/2005 Via Dep.), at 43:22 - 44:3; BIC/BIPi Fauci Exhibit 103 (12/12/2008 Carr-Hall Dep.), at 63:13 - 64:8) Robert Sykora, who was a BIPI employee with responsibility for promoting Roxane and BIPI products, prepared a series of slides to present to

Roxane's palliative care sales force in anticipation of the launch of Roxane's 15/30 mg Roxicodone tablets. (BIC/BIPI Fauci Exhibit 36 (11/2/2005 Sykora Dep.), at 22:20 - 23:5; BIC/BIPI Fauci Exhibit 12 (12/4/2008 Sykora Dep.), at 133:7 - 135:13. One slide noted that Roxicodone 15 mg and 30 mg was typically more profitable for pharmacies to dispense. (BIC/BIPI Fauci Exhibit 104, at BOEH01301726)

76. Roxane employees were responsible for providing its brand/branded generic prices to the pricing compendia. (*See, e.g.*, Tab 78, 5/10/07 Waterer Dep. Ex. 35 (Red Book 14084-85); Tab 77, 5/10/07 Waterer Dep. Ex. 34 (Red Book 14071-83); *see also* pricing communications listed in ¶ 63)

United States' Response: Disputed. Gregg Ciarelli testified that from 1997 through 2000, he had "ongoing responsibility" for reporting prices to First Data Bank for Roxane's branded products. (BIC/BIPI Fauci Exhibit 52 (7/25/2007 Ciarelli Dep.), at 22:10 - 24:10, 28:17 - 29:4, 49:17 - 49:21) Mr. Ciarelli was employed and paid by BIPI for his entire tenure with Boehringer Ingelheim. (BIC/BIPI Fauci Exhibit 51 (6/26/2002 Ciarelli Dep.), at 9:17 - 10:11, 50:6 - 50:13)

77. Roxane also had its own field sales force responsible for promoting its palliative care and HIV products, mainly to physicians, and they reported to Jerry Hart, as Director of RLI Brand Sales. (Tab 22, 8/5/08 Shaffer Dep. 363; Tab 86, RLI-ORG00000082 (1998 Roxane Sales Department Organization Chart)) In 1999, the palliative care and HIV divisions of the RLI Brand sales group split; the HIV group continued to report to Mr. Hart, and the palliative care group began reporting to Mark Shaffer as Director of Sales for Palliative Care. (Tab 21, 5/21/08 Shaffer Dep. 54; Tab 84, RLI-ORG00000083 (1999 Roxane Sales Department Organization Chart)) The HIV sales force had roughly 35-50 members, and the palliative care sales force had roughly 50 members. (Tab 25, 10/18/05 Via Dep. 87)

United States' Response: Undisputed, except the palliative care sales force was not exclusively responsible for promoting these products. (*See supra* United States' Response to Paragraph 75)

78. In late 1998, organizational changes were made to leverage the expertise and experience in marketing brand name products of several BIPI-based employees for the benefit of Roxane's brand and branded generic products, and certain Roxane employees in marketing and sales for branded generics began to report functionally to designated people at BIPI. (Tab 2, 10/31/08 Berkle Dep. 59-60). Specifically,

- Gary Ellexson, Director of Roxane's Branded and Specialty Marketing, began reporting to Greg Fulton, who became head of BIPI/RLI Branded Marketing. (Tab 63, 10/31/08 Berkle Dep. Ex. 27 at RLI-AWP-00161739 (10/23/98 Reorganization Memo); Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Roxane Laboratories, Inc. Budget 1999 Organizational Chart) (Budget 1999 Org. Chart)) Roxane's Branded Marketing staff continued to report to Ellexson. (*Id.*)
- Jerry Hart, Director of Roxane Sales, began reporting to Jim King, who became head of BPI/RLI Branded Sales. Roxane's field sales force continued to report to Hart. (Tab 63, 10/31/08 Berkle Dep. Ex. 27 at RLI-AWP-00161739 (10/23/98 Reorg. Memo); Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Budget 1999 Org. Chart))
- BIPI and RLI Contract Administration continued to have departments at both BIPI and Roxane, but management was streamlined. (Tab 63, 10/31/08 Berkle Dep. Ex. 27 at RLI-AWP-00161740 (10/23/98 Reorganization Memo)) John Powers, Roxane's Director of Contracts, began reporting to Gregg Ciarelli, who became head of Contracting and Marketing Controlling. Powers, was responsible for day-to-day management of the groups in both locations. (*Id.*; Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Budget 1999 Org. Chart))

United States' Response: The United States does not dispute that organizational changes in the Business Unit were made in 1998 or that, in accord with such changes, Roxane employees "functionally" reported to employees at BIPI. The United States disputes this paragraph to the extent it implies that Roxane employees did not report to their BIPI counterparts prior to 1998. The Employee Bulletin announcing the 1998 organizational changes made clear that such changes built on steps taken "in the past two years to increase the level of Business Unit collaboration and focus across organization." (BIC/BIPI Fauci Exhibit 18; *see generally* United States' Responses to Paragraphs 7 and 53)

Further answering, the United States does not dispute that Mr. Fulton, Mr. King and Mr. Ciarelli supervised employees at Roxane. The United States also does not dispute that Mr. Powers reported to Mr. Ciarelli at BIPI, and that Mr. Powers managed the contracts functions for both Roxane and BIPI. The United States disputes, however, that Roxane and BIPI continued to

have separate contracts departments. Beginning in at least 1998, the Contracts Functions was located at BIC and BIPI's headquarters in Connecticut. (BIC/BIPI Fauci Exhibit 56 (11/9/2004 Paoletti Dep.), at 90:15 - 92:6) Moreover, Mr. Powers testified that beginning in 1996 "decisions were made that the Roxane business and the Boehringer business should get closer together in terms of management, that the two companies shouldn't be run as two separate entities any longer." (BIC/BIPI Fauci Exhibit 47 (2/4/2003 Powers Dep.), at 40:14 - 42:1)

79. Fulton, King, and Ciarelli provided an additional line-of-sight in the organization, but Roxane employees continued to handle the day-to-day operations of its brand and branded generic lines, including sales and marketing. (Tab 2, 10/31/08 Berkle Dep. 59-60 ("Those people within the Roxane business entity did report functionally to designated people within the BIPI organization, but the day-to-day operations were still conducted by Roxane people."); *Id.* 191-192 ("it made sense to combine . . . at certain levels the reporting relationship to . . . allow Roxane to benefit from the expertise within BIPI . . . I emphasize that the day-to-day operations were conducted for the Roxane . . . branded generic products within the Roxane structure."))

United States' Response: The United States does not dispute that Mr. Fulton, Mr. King and Mr. Ciarelli supervised Roxane employees. The United States disputes any implication that Mr. Fulton, Mr. King and Mr. Ciarelli were not involved in "day-to-day operations" at Roxane. Further answering, Mr. King and Mr. Ciarelli were on the pricing committee and exercised regular and formal authority in approving Roxane's prices, including AWP's. (*See supra* United States' Response to Paragraph 53) Moreover, Mr. Ciarelli had "ongoing" responsibility for reporting AWP's for Roxane's branded generic products. (BIC/BIPI Fauci Exhibit 52 (7/25/2007 Ciarelli Dep.), at 22:10 - 24:10, 28:17 - 29:4, 49:17 - 49:21)

80. In 2000, the decision was made to divest Roxane's palliative care and HIV line so that it could focus its business on generic products. Marketing operations for the palliative care drugs began to wind down, and at the end of 2000, the sales force dissolved and Roxane no longer had sales people promoting those products. (Tab 21, 5/21/08 Shaffer Dep. 225-226, 355-356; Tab 10, King Dep. 197) Roxane also stopped promoting Viramune, a brand name HIV drug that it licensed from BIPI. Viramune was transferred back to BIPI in 2001. (Tab 42, BOEH04600348-52, BOEH04600353-62 (Roxane Unanimous Consents); Tab 15, McIntyre Dep. 158-159)

United States' Response: Undisputed. Further answering, this decision was first made at a BIC/BIPI Board meeting. (*See supra* United States Response to Paragraph 27)

81. On September 28, 2001, Roxane divested Roxicodone, Oramorph, Roxanol, and several other palliative care drugs to Elan Pharmaceuticals pursuant to an Asset Purchase Agreement. (Tab 53, BOEH01046045-6092 (Elan Asset Purchase Agreement); (Tab 42, BOEH04600369-74 (Roxane Unanimous Consents)) Roxane booked a \$200 million payment from Elan for the divested drugs. (Tab 48, BOEH02675446-72 at 50-52, 58 (Commentary To The Financial Statements For Year End 12/31/01))

United States' Response: Undisputed. Further answering, this decision was first made at a BIC/BIPI Board meeting. (*See supra* United States Response to Paragraph 27)

82. From this point on, Roxane's product line was almost exclusively generic and BIPI-based employees provided no more support for Roxane's marketing or sales. (Tab 2, 10/31/08 Berkle Dep. at 229; Tab 1, 1/27/05 Berkle Dep. at 155)

United States' Response: The United States does not dispute that following the September 2001 divestiture of the palliative care line, BIPI had less involvement with Roxane's business.

The paragraph is otherwise disputed, and is not supported by the cited authority.

V. Testimony of Professor Jonathan R. Macey

83. Jonathan Macey is the Sam Harris Professor of Corporate Law, Corporate Finance, and Securities Law at the Yale Law School, and Professor in the Yale School of Management. He currently serves as Deputy Dean of the Yale Law School, and is a member of the Board of Directors of the Yale Law School Center for the Study of Corporate Governance and a Member of the Faculty Advisory Group of Yale's Millstein Center for Corporate Governance Performance. Professor Macey has served on the boards of directors of numerous companies, has taught many joint business and law school classes on corporate governance and business organizations, and has written extensively on those topics. (Tab 88, Macey Dep. Ex. 1 (Macey CV))

United States' Response: Undisputed.

84. His areas of expertise are "corporate governance, corporate control, ordinary and standard business practices among, parent, subsidiaries and affiliate corporations, and economic and public policy related to corporate groups and relationships among parent, subsidiary and affiliate corporations." (Tab 11, 5/19/09 Macey Dep. 45) He has studied, written and taught extensively on these topics. (Tab 88, Macey Ex. 1 (Macey CV))

United States' Response: Undisputed.

85. Professor Macey analyzed the corporate governance issues related to the interactions and relationships between the BIC, BIPI and Roxane, including whether the companies “operated as separate and independent corporate entities” and whether the “relationships were consistent with ordinary and customary business practices” as well as sound public policy. (Tab 11, Macey Dep. 47-48) In the course of his work he looked at, among other information, the history of the companies, the relationships and interactions between the entities and how they evolved over time, the corporate formalities followed by the companies and the capitalization and financial condition of Roxane. (*Id.* 53-54)

United States' Response: The United States does not dispute that Professor Macey purports to offer opinions on whether BIC, BIPI and Roxane “operated as separate and independent corporate entities” and whether the relationships between the defendants “were consistent with ordinary and customary business practices.” The United States disputes the materiality of any such conclusions, however, as Professor Macey’s testimony that the defendants are “separate and independent” entities is inadmissible opinion evidence. The issue of whether evidence is sufficient to pierce the corporate veil “is a question of law” and, in the First Circuit, piercing the corporate veil is appropriate “if one corporation is not an independent entity, but rather the mere alter ego of another.” *Brotherhood of Locomotive Engineers v. Springfield Terminal Ry. Co.*, 210 F.3d 18, 25 (1st Cir. 2000). Professor Macey’s testimony is squarely addressed to a legal conclusion, and therefore immaterial and inadmissible, as the First Circuit holds that “[i]t is not for witnesses to instruct the jury as to applicable principles of law, but for the judge.” *See Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92 (1st Cir. 1997) (*citing* *United States v. Newman*, 49 F.3d 1, 7 (1st Cir. 1995)). Moreover, whether or not the relationships among the defendants were consistent with “ordinary and customary business practices” or “sound public policy” is irrelevant to BIC or BIPI’s liability under the False Claims Act.

86. Professor Macey’s opinion, based on “[his] research and practical experience in the area of corporate governance” is that “the relationship between BIC, as a parent holding

company, and Roxane was well within the normal range with respect to corporate governance relationships and corporate formalities and corporate separateness and maintaining an actual corporate identity . . . with respect to both of those entities.” On this same basis, Professor Macey’s opinion is that the corporate relationships between BIPI and BIC, and BIPI and Roxane, are normal and typical. (*Id.* 51-52)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85)

87. In reaching his opinion that the relationships among the defendants were normal and typical, Professor Macey’s methodology involved “comparing the actual interactions among these companies . . . with ordinary and customary business practice and . . . industry norm” and then looking at the “public policy benefits and costs associated with those” to determine whether the relationships among BIC, BIPI, and Roxane were “one, normal and consistent with . . . U.S. corporate practice, and two, whether they presented any . . . externality or cost or policy issues.” (*Id.* 54-55) According to Professor Macey, corporate relationships are considered normal and typical if “they are consistent with standard practice with what we observe other similarly situated, similarly organized corporations doing . . . [a]nd two, whether there are any kind of special problems associated with a particular form of or particular pattern of behavior among parents and subsidiaries or sibling corporations.” (*Id.* 55)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85)

88. Professor Macey’s basis for what constitutes a normal and typical corporate relationship is “what corporations actually do.” Professor Macey testified “I study corporate relationships, I study corporate groups, and I study the interactions among these groups from a wide variety of perspectives and so it’s a matter of my research and experience as to . . . what it is that we observe in . . . the landscape of U.S. business.” (*Id.* 58-59)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See*

supra United States’ Response to Paragraph 85)

89. Professor Macey testified that it is normal and typical for holding companies, or one subsidiary in a corporate family – like BIPI – to provide shared services for the other subsidiaries, such as legal IT, financial and accounting services. (*Id.* 68-69)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85)

90. Professor Macey also noted that it is “beyond routine . . . for personnel within subsidiaries to be actively involved in the management and operations of sibling companies because . . . it’s extremely common to see people in these various corporate groups wear a multitude of hats.” (*Id.* 74) It is also “extremely common for subsidiary companies to contract with each other and to have interactions of a variety of kinds. . . .” (*Id.*) Both practices are common because it allows the “expertise of one . . . or the services of one” to be “utilized for the benefit” of another.” (*Id.* 74-75)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85)

91. Based on this benchmark of typical corporate relationships, Professor Macey concluded that when a BIPI officer, Sheldon Berkle, held certain oversight responsibilities over certain Roxane products, “he wasn’t really doing anything by or on behalf of BIPI” and would not be characterized as a BIPI agent. (*Id.* 78-79) Professor Macey concluded that “he was wearing two hats and he was operating as a Roxane person.” (*Id.* 79)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85) In addition, Professor’s Macey testimony that Mr. Berkle “wasn’t really doing anything by or on behalf of BIPI” and “would not be

characterized as a BIPI agent” lacks foundation. Determining whether an agency relationship exists is a multi-factored analysis properly left to the jury. *See Camacho v. Puerto Rico Ports Authority*, 369 F.3d 570, 574 (1st Cir. 2004). Mr. Berkle himself testified that he never was an officer at Roxane and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 53:1 - 53:18)

92. Professor Macey observed that the particular facts of this case made it “extremely easy to tell, for example, when Mr. Berkle is acting for Roxane and when Mr. Berkle is acting for BIPI”, because Roxane’s products were separate and distinct from BIPI’s drugs. As such, Mr. Berkle’s decisions regarding particular drugs would not apply to both companies. (*Id.* 81-82)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85) In addition, Professor’s Macey testimony lacks foundation. Determining whether an agency relationship exists is a multi-factored analysis properly left to the jury. *See Camacho v. Puerto Rico Ports Authority*, 369 F.3d 570, 574 (1st Cir. 2004). Mr. Berkle himself testified that he never was an officer at Roxane and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 53:1 - 53:18)

93. Professor Macey determined that certain BIPI employees who were given responsibilities with regard to Roxane’s brand and branded generic products in 1998, “took on . . . a second hat” and “became agents of Roxane.” (*Id.* 159-161) To the extent that individuals such as Mr. Leonetti, Mr. Fulton, Mr. Ciarelli, and Mr. King were involved in the high level supervision of Roxane’s brand and branded generic products, in that capacity, “they were acting as agents of Roxane.” (*Id.* 166-167) Professor Macey noted that “virtually without exception one observes these kind of dual relationships which involve somebody who is accepting one paycheck from one company, who is kind of seconded . . . or acting as an agent wearing a second hat with respect to a second company.” (*Id.* 167) Macey also testified that in those situations where employees serve dual roles at two companies, the “overwhelming business practice in the United States is to have people receive a single paycheck.” (Tab 12, 5/20/09 Macey Dep. 269-270)

United States’ Response: The United States does not dispute that Professor Macey offered the

opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI's liability under the False Claims Act. (*See supra* United States' Response to Paragraph 85) In addition, Professor's Macey testimony lacks foundation. Determining whether an agency relationship exists is a multi-factored analysis properly left to the jury. *See Camacho v. Puerto Rico Ports Authority*, 369 F.3d 570, 574 (1st Cir. 2004).

Moreover, Mr. King testified that although he supervised Roxane sales personnel, he was employed by BIPI for his entire career and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 11:13 - 12:4, 15:2 - 15:23, 25:15 - 26:8) Similarly, Mr. Ciarelli testified that he was employed and paid by BIPI for his entire tenure with Boehringer Ingelheim. (BIC/BIPI Fauci Exhibit 51 (6/26/2002 Ciarelli Dep.), at 9:17 - 10:11, 50:6 - 50:13) Likewise, Mr. Leonetti worked for BIPI, and there is no evidence he was ever a Roxane agent or employee. (BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 219:19 - 220:7; BIC/BIPI Fauci Exhibit 54 (4/3/2003 Rowenhorst Dep.), at 125:15 - 126:6)

94. Professor Macey testified that in some situations it could be difficult to tell which hat an employee is wearing at a given time, but here "we can tell on whose behalf these people are operating as agent because we know, we can see whose company's products they were involved with . . ." (Tab 11, 5/19/09 Macey Dep. 167-68)

United States' Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, *see supra* United States' Responses to Paragraphs 85, 92, and 93.

95. Professor Macey also examined Roxane's balance sheets and profit and loss statements to determine whether Roxane was adequately capitalized over time. (Tab 12, 5/20/09 Macey Dep. 297) Professor Macey has been qualified to serve as a member of a public corporation's audit committee, and in that capacity, is responsible for reviewing the company's financial statements and ensuring they are in accordance with appropriate accounting principles. (*Id.* 299) In this case, Professor Macey evaluated a number of different factors relevant to a

company's level of capitalization, such as whether there were incursions on Roxane's initial capitalization and capital surplus, the amount of Roxane's retained earnings, Roxane's dividend policy, and Roxane's average debt-to-equity ratio compared with average debt-to-equity ratios among other pharmaceutical firms. (*Id.* 318-20, 336-337). Professor Macey calculated Roxane's average retained earnings between 1995 and 2005, and Roxane's average dividend payments between 1995 and 2005. (*Id.* 338) Based on this analysis, Professor Macey concluded that Roxane was sufficiently capitalized during the relevant time period. (*Id.* 296, 311-312)

United States' Response: The United States does not dispute that Professor Macey purports to offer an opinion that "Roxane was sufficiently capitalized during the relevant time period." The United States disputes the materiality of this paragraph, however, as Professor Macey's opinion lacks foundation. In addition, Roxane's "average retained earnings" and its "average" dividend payments have no bearing on whether or not Roxane was adequately capitalized at any particular point in time, or is adequately capitalized now.

Further answering, Professor Macey did not compare Roxane's level of capitalization to that of any other pharmaceutical companies. (BIC/BIPI Fauci Exhibit 61 (5/20/2009 Macey Dep.), at 320:2 - 320:6. Instead, Professor Macey compared Roxane's capitalization to "an industry benchmark," under which Professor Macey claimed it was not unusual to see debt to equity ratios in the "5 to 1 to 10 to 1 range." (*Id.*, at 318:3 - 320:20). Professor Macey's understanding of this benchmark is based only on his recollection of literature in the field. (*Id.*) From 1996 through 2001, Roxane's equity consistently exceeded total liabilities; that is, Roxane's liabilities to equity ratio was consistently *less than one to one*. (*See supra* in the United States' Responses to Paragraphs 36 and 39) This is consistent with the level of capitalization observed at Roxane's competitors. Specifically, four of the six Roxane competitors for which the United States was able to obtain financial data had liabilities to equity ratios of less than 1.5 to 1 throughout the time frame. (BIC/BIPI Fauci Exhibit 101 (Declaration of Patrick Ormond), ¶¶ 17 - 19)

Roxane's liabilities to equity ratio grew to over 5 to 1 in 2002, following Roxane's payment of a \$320 million dividend to BIC in November of that year. Payment of that dividend constituted a departure from Roxane's past practices, and left Roxane significantly less capitalized than many of its competitors. Moreover, payment of the dividend apparently violated Boehringer Ingelheim's own guidelines, which provide dividends are appropriate if a company's debt to equity ratio is less than 1.5 to 1. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 210:4 - 211:4). Following payment of the dividend, Roxane's liabilities were over *fives times* greater than its total equity.

96. Professor Macey's opinion, based on the totality of the record, is that Roxane operated as an independent company. (Tab 11, 5/19/09 Macey Dep. 87-88) As a distinct corporate entity, Professor Macey determined that Roxane did "maintain operational control over its business" and that included "control over the pricing and marketing of its products." (*Id.* 122-123)

United States' Response: The United States does not dispute that Professor Macey purports to offer an opinion that Roxane "operated as an independent company." The United States disputes the materiality of this paragraph, however, as Professor Macey's testimony that the defendants are "separate and independent" entities is inadmissible opinion evidence. The issue of whether evidence is sufficient to pierce the corporate veil "is a question of law" and, in the First Circuit, piercing the corporate veil is appropriate "if one corporation is not an independent entity, but rather the mere alter ego of another." *Brotherhood of Locomotive Engineers v. Springfield Terminal Ry. Co.*, 210 F.3d 18, 25 (1st Cir. 2000). Therefore, Professor Macey's testimony is squarely addressed to a legal conclusion, and the First Circuit holds that "[i]t is not for witnesses to instruct the jury as to applicable principles of law, but for the judge." *See Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92 (1st Cir. 1997) (*citing* *United States v. Newman*, 49 F.3d 1, 7 (1st Cir. 1995)). Further answering, *see infra* United States' Responses to Paragraphs 85, 92 and 93.

DATED: August 28, 2009

Respectfully submitted,

MICHAEL F. HERTZ
DEPUTY ASSISTANT ATTORNEY GENERAL

MICHAEL J. LOUCKS
ACTING UNITED STATES ATTORNEY

By: /s/ James J. Fauci
GEORGE B. HENDERSON, II
BARBARA HEALY SMITH
JAMES J. FAUCI
Assistant U.S. Attorneys
United States Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3272

JOYCE R. BRANDA
DANIEL R. ANDERSON
LAURIE A. OBEREMBT
Civil Division
Commercial Litigation Branch
P. O. Box 261, Ben Franklin Station
Washington, D.C. 20044
(202) 514-3345

For the relator, Ven-A-Care of the Florida
Keys, Inc.,
JAMES J. BREEN
The Breen Law Firm, P.A.
Suite 260
5755 North Point Parkway
Alpharetta, Georgia 30022
Phone (770) 740-0008

SUSAN S. THOMAS
GARY L. AZORSKY
ROSLYN G. POLLACK
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103
Telephone: 215-875-3000

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: August 28, 2009

/s/ James J. Fauci
JAMES J. FAUCI
Assistant U.S. Attorney